

Center for Nuclear Waste Regulatory Analyses

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Contract No. NRC-02-93-005
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Date 9/1/94
DCS*

U.S. Nuclear Regulatory Commission
ATTN: Mr. William Belke
High-Level Waste Projects and Quality Assurance
Office of Nuclear Material Safety and Safeguards
TWFN, Mail Stop T7J9
Washington, D.C. 20555

Subject: Evaluation of QA Requirements Applicability to CNWRA Activities

Reference: Administrative Item 5702-331-416

Dear Mr. Belke:

Enclosed is a copy of the subject report. In this report we have documented our evaluation in regard to (i) application of QA requirements based on the importance of activities and (ii) identification of controls appropriate to the missions of the NRC and CNWRA.

The report was developed as requested by Kenneth Hooks of your office, and follows discussions with you and other members of the Division of Waste Management staff. After you have had opportunity to review this document, we would be pleased to discuss it with you.

Please contact me (210) 522-5149 if you have any questions.

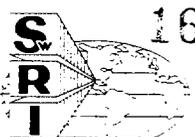
Very truly yours,

Bruce Mabrito
Bruce Mabrito
Director
Quality Assurance

BEM/ac
enclosure

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RE-EVALUATION OF QUALITY ASSURANCE REQUIREMENTS AT THE CNWRA

INTRODUCTION

The NRC tasked the CNWRA to re-evaluate quality assurance requirements that have been applied to technical activities and products of the CNWRA. This task was motivated by questions at NRC regarding whether quality assurance program controls were being properly applied to software development. NRC noted that early phases of computer code development had not been controlled, controls were being applied only to certain codes, and the extent of controls was less than was typically found with DOE participants conducting similar activities. This paper attempts to clarify the basis for the application of QA program controls at the CNWRA.

BACKGROUND

Contractually, the CNWRA is obligated to implement a QA program addressing the applicable portions of 10 CFR Part 50, Appendix B. Intentionally, these are the same criteria applied to the DOE for a High-Level Waste Repository in 10 CFR Part 60. Although an understanding had been reached with NRC program management that the CNWRA would implement a quality program equivalent to that of the DOE for similar activities, as the CNWRA has matured and the scope of work has been better defined over the years, differences in both the nature of the activities and the end use of the resulting products have become more apparent.

In the past, the CNWRA QA program has been applied to activities "important to licensing," without distinction of relative importance within this broad classification. One exception is the application of software configuration controls only to codes which are expected to be utilized in compliance determination.

Central to the re-evaluation of the application of 10 CFR Part 50, Appendix B QA requirements at the CNWRA is an objective determination of what constitutes "similar activities." Many have interpreted this phrase quite literally, that is, without regard to the use of the data, analyses, and interpretations which would result from those activities. This premise needs to be re-evaluated in light of the profoundly different missions and roles of the DOE and its contractors, on the one hand, and the NRC and its contractors (including CNWRA), on the other.

RE-EVALUATION OF QA PROGRAM APPLICABILITY

In interpreting 10 CFR Part 50, Appendix B for application to research and technical assistance activities, three principles are commonly applied to select the appropriate QA controls and determine their range of applicability. First, consideration must be given to the importance of the specific activity, product, or function. Historically, this consideration has been expressed in terms of "important to safety." In the repository program, a perspective of "important to licensing" is more appropriate for the regulatory agency and its contractors. Second, attention must be given to the unique mission of the organization to which the controls would be applied. CNWRA has attempted to take an approach which is (i) consistent with its understanding of the NRC role and responsibilities under the NWPA, and (ii) sound in the context of NRC reactor licensing practices. Simply stated, NRC and its contractors should not take on the burden of the license applicant. Consequently, data, codes, methods, analysis, etc. that NRC and its contractors uniquely develop for direct use in compliance determination (including pre-licensing and license application reviews) should be subject to more extensive QA controls than for less important

activities. Third, QA controls should be selected and applied which provide measurable value added. In other words, controls should be applied which assure or enhance the quality of an activity or product beyond what would be obtained in the absence of such controls.

PROPOSED QUALITY REQUIREMENTS APPLICATION STRATEGY

10 CFR Part 50, Appendix B, Criterion II indicates that the QA program should be applied to an extent consistent with the importance to safety (for the CNWRA role in support of NRC, this is taken as importance to licensing). To implement a strategy of applying controls consistent with importance, first a basis for determining importance is necessary. For the CNWRA, data, codes, methods, and analysis uniquely developed by NRC and its contractors for direct use in compliance determination (including pre-licensing and license application reviews) are clearly more important than those that generally support the staff capability to conduct licensing related activities. Second, controls appropriate to the role of the regulator (as opposed to those appropriate to the licensee) must be identified and implemented.

The determination of importance could be performed in the quality planning phase of CNWRA Operations Plan and Research Project Plan development. A group of CNWRA technical management, QA, and principal investigators would evaluate each task or portion of a task, and categorize each activity based on importance as listed below.

- Quality Affecting - Generally Important to Licensing: Activities and products not expected to be directly applied in determining compliance of DOE's License Application. These activities generally support the development of the staff's capability to respond to the DOE in pre-licensing activities and to conduct license application compliance reviews. CNWRA Technical Operating Procedures and Quality Assurance Procedures implementing good scientific and engineering practices appropriate to the scope of work would be applied. Procedures implementing good practices provide controls sufficient to assure the quality of CNWRA laboratory and field data development and acquisition.
- Quality Affecting - Important to Compliance Determinations: Activities whose products (e.g., computer codes and other analysis methods, data) are expected to be directly used to analyze DOE License Application data or for comparison to DOE License Application data and results. All CNWRA Technical Operating Procedures and Quality Assurance Procedures, including those implementing good practices, appropriate to the scope of work would be applied.
- Non-quality Affecting: Administrative or financial activities that do not impact compliance determinations or the development of staff capabilities to support licensing and pre-licensing activities.

Controls proposed as appropriate to the role of the CNWRA in support of the NRC are as follows.

- Data: Those data directly used in compliance determinations that are not included in DOE's license application shall be qualified consistent with the guidance of NUREG-1298, by one of the methods described in CNWRA QAP-015. Very little, if any, data is expected to require CNWRA qualification as all should be qualified by DOE.

- Computer Codes: Scientific and engineering codes directly used in compliance determination shall be under configuration control, tests shall be performed to assure proper operation of the code, and code documentation shall be prepared or obtained. For codes developed by the CNWRA or NRC, design documents shall be prepared. The controls provided by CNWRA TOP-018 address these requirements, as well as the essential criteria of full software life-cycle requirements documents (e.g., NUREG/CR-4640, Handbook of Software Quality Assurance Techniques Applicable to the Nuclear Industry).
- Methods and Analyses: Methods and analyses not involving complex computer codes that are used directly in compliance determination shall be verified as described in CNWRA QAP-014, Documentation and Verification of Routine Calculations.

As part of the quality planning process, CNWRA Operating Procedures appropriate to the activities and their importance would be identified as applicable, and subsequently implemented for the specific activity. Planned surveillance would verify proper implementation of the applicable Operating Procedures. Existing CNWRA Operating Procedures applicable to Quality Affecting - Important to Compliance Determinations and applicable to both quality affecting categories are listed in the following table.

Operating Procedures Applicable to Quality Affecting - Important to Compliance Determination Activities

- QAP-003 STANDARD PROCUREMENT DOCUMENT QUALITY REQUIREMENTS FOR SCIENTIFIC INVESTIGATIONS, INTERPRETATIONS AND ANALYSIS SERVICES SUPPLIERS
- QAP-006 ACCEPTANCE AND IDENTIFICATION OF PROCURED ITEMS, SAMPLES, AND SOFTWARE
- QAP-014 DOCUMENTATION AND VERIFICATION OF ROUTINE CALCULATIONS
- QAP-015 QUALIFICATION OF EXISTING DATA
- QAP-016 PROCUREMENT CONTROL
- TOP-001-11 DEVELOPMENT OF COMPLIANCE DETERMINATION STRATEGIES
- TOP-001-13 DEVELOPMENT OF COMPLIANCE DETERMINATION METHODS
- TOP-001-15 RPD LOADING, VERSION, AND CHANGE CONTROL
- TOP-015 PROCEDURE FOR DECISION ANALYSIS
- TOP-018 PROCEDURE FOR CONFIGURATION MANAGEMENT AND CONTROL OF SCIENTIFIC AND ENGINEERING COMPUTER CODES

Operating Procedures Applicable to All Quality Affecting Activities

- QAP-001 SCIENTIFIC AND LABORATORY NOTEBOOK CONTROL
- QAP-002 REVIEW OF CNWRA DOCUMENTS, REPORTS, PAPERS AND PRESENTATION MATERIALS
- QAP-004 SURVEILLANCE CONTROL
- QAP-005 QUALITY INDOCTRINATION AND TRAINING
- QAP-007 PROFESSIONAL PERSONNEL QUALIFICATION
- QAP-008 DOCUMENT CONTROL
- QAP-009 NONCONFORMANCE CONTROL
- QAP-010 CORRECTIVE ACTION
- QAP-011 AUDITS

Procedures Applicable to All Quality Affecting Activities

- QAP-012 RECORDS CONTROL
- QAP-013 QUALITY PLANNING
- TOP-003-01 PROCEDURE FOR PREPARATION ELECTROCHEMICAL/CORROSION TEST SPECIMENS
- TOP-004 PROCEDURE FOR CONTROL, PREPARATION, AND CHARACTERIZATION OF GEOLOGICAL MATERIALS
- TOP-004-01 PROCEDURE FOR PREPARATION OF THIN SECTIONS OF GEOLOGICAL MATERIALS
- TOP-004-02 PROCEDURE FOR QUALITATIVE X-RAY POWDER DIFFRACTION ANALYSIS OF GEOLOGICAL MATERIALS
- TOP-005 PROCEDURE FOR ZEOLITE ION EXCHANGE EXPERIMENTS
- TOP-006 PROCEDURE FOR OBTAINING SEISMIC ROCK MECHANICS TEST SPECIMENS FROM THE FIELD
- TOP-007 PROCEDURE FOR ASSEMBLING AND TESTING JOINTED-ROCK TUFF SPECIMENS USING A DYNAMIC SIMULATOR WHICH PRODUCES DYNAMIC SHEAR AND COMPRESSIVE NORMAL LOADS
- TOP-008 CONDUCTING AND VERIFYING CYCLIC POLARIZATION TESTS
- TOP-009 CONDUCTING AND VERIFYING POTENTIODYNAMIC POLARIZATION TESTS
- TOP-010 PREPARING SIMULATED J-13 WATER AND ITS MODIFICATIONS
- TOP-011 PROCEDURE FOR ASSEMBLING AND INSTALLING HYDRAULIC ANCHOR BOREHOLE EXTENSOMETERS
- TOP-013 TECHNICAL OPERATING PROCEDURE FOR SPECTROPHOTOMETRIC ANALYSIS OF ALUMINUM
- TOP-014 TECHNICAL OPERATING PROCEDURE FOR SPECTROPHOTOMETRIC ANALYSIS OF SILICA
- TOP-016 TECHNICAL OPERATING PROCEDURE FOR FIELD COLLECTION OF GEOLOGIC SAMPLES
- TOP-017 FIELD COLLECTION OF WATER SAMPLES
- TOP-019 PREPARATION OF GROUND BOROSILICATE GLASS SPECIMENS

Procedures Applicable to All Quality Affecting Activities

- TOP-020 CLEANING OF STAINLESS STEEL LEACHING VESSELS
- TOP-021 PRODUCT CONSISTENCY TEST (PCT) FOR GLASS
- TOP-012 PROCEDURE FOR IDENTIFICATION, CONTROL, STORAGE, HANDLING,
SHIPPING, AND ARCHIVING OF SAMPLES