

**CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES  
QUALITY ASSURANCE MANUAL**

Rev. 2, Change 7

March 1995

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**EFFECTIVITY AND APPROVAL**

Revision 2 of this procedure became effective on 6/1/90. This procedure consists of the pages and changes listed below.

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| Introduction   | i.1             | 5             | 10/21/93                 |
| Introduction   | i.2             | 0             | 6/1/90                   |
| Introduction   | i.3             | 7             | 3/24/95                  |
| 1              | 1.1             | 4             | 4/21/92                  |
| 1              | 1.2             | 0             | 6/1/90                   |
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| 1              | 1.8             | 7             | 3/24/95                  |
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| 2              | 2.1-2.2         | 0             | 6/1/90                   |
| 2              | 2.3             | 7             | 3/24/95                  |
| 2              | 2.4             | 4             | 4/21/92                  |
| 2              | 2.5             | 7             | 3/24/95                  |
| 2              | 2.6             | 7             | 3/24/95                  |
| 2              | 2.7             | 5             | 10/21/93                 |
| 2              | 2.8-2.9         | 2             | 5/9/91                   |
| 3              | 3.1-3.10        | 7             | 3/24/95                  |
| 4              | 4.1             | 0             | 6/1/90                   |
| 5              | 5.1-5.2         | 4             | 4/21/92                  |
| 6              | 6.1             | 4             | 4/21/92                  |
| 6              | 6.2             | 2             | 5/9/91                   |
| 6              | 6.3             | 4             | 4/21/92                  |
| 6              | 6.4             | 0             | 6/1/90                   |
| 6              | 6.5-6.6         | 4             | 4/21/92                  |
| 6              | 6.7             | 2             | 5/9/91                   |
| 6              | 6.8             | 1             | 10/5/90                  |

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**Approvals**

| Director of QA       | Date           | CNWRA President   | Date           |
|----------------------|----------------|-------------------|----------------|
| <i>Samuel M. ...</i> | <i>3/24/95</i> | <i>Wesley ...</i> | <i>3/24/95</i> |

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| 7              | 7.1-7.2         | 5             | 10/21/93                         |
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| 8              | 8.2             | 3             | 9/10/91                          |
| 8              | 8.3             | 2             | 5/9/91                           |
| 9              | 9.1             | 0             | 6/1/90                           |
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| 9              | 9.3             | 0             | 6/1/90                           |
| 10             | 10.1            | 0             | 6/1/90                           |
| 11             | 11.1            | 0             | 6/1/90                           |
| 12             | 12.1            | 1             | 10/5/90                          |
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| 12             | 12.4            | 3             | 9/10/91                          |
| 12             | 12.5            | 7             | 3/24/95                          |
| 12             | 12.6            | 0             | 6/1/90                           |
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| 13             | 13.1            | 0             | 6/1/90                           |
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| 14             | 14.1            | 0             | 6/1/90                           |
| 15             | 15.1-15.2       | 1             | 10/5/90                          |
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| 16             | 16.1            | 1             | 10/5/90                          |
| 16             | 16.2            | 3             | 9/10/91                          |
| 16             | 16.3            | 2             | 5/9/91                           |
| 17             | 17.1            | 2             | 5/9/91                           |
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| 17             | 17.3-17.5       | 2             | 5/9/91                           |
| 18             | 18.1            | 1             | 10/5/90                          |
| 18             | 18.2            | 3             | 9/10/91                          |
| 18             | 18.3            | 1             | 10/5/90                          |
| 18             | 18.4            | 2             | 5/9/91                           |
| Appendix I     | I.1             | 1             | 10/5/90                          |
| Appendix I     | I.2-I.5         | 0             | 6/1/90                           |
| Appendix I     | I.6-I.9         | 6             | 02/04/94                         |
| Appendix I     | I.10            | 0             | 6/1/90                           |

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**INTRODUCTION**

The Center for Nuclear Waste Regulatory Analyses (the Center or CNWRA) is chartered to provide sustained high quality technical assistance and research in support of the United States Nuclear Regulatory Commission (NRC) waste management program under the Nuclear Waste Policy Act of 1982, as amended (NWPA). The Center is committed to maintain an organization characterized by high technical competence, permanence, stability, and the capability to provide independent, objective recommendations on complex technical issues. Founded in 1987, the Center is a not-for-profit Federally Funded Research and Development Center organized to serve the NRC, and is structured as a division of Southwest Research Institute (SwRI or the Institute).

The requirement for a Center quality assurance (QA) program originates with the contract between the Center and the NRC. Specifically, a QA program is needed to address the unique work of the Center. Since Title 10, Code of Federal Regulations, Part 50, Appendix B (Appendix B), "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," is invoked by Subpart G of 10 CFR Part 60, the regulatory criteria for high level waste disposal, the CQAM shall comply with and implement the appropriate criteria of Appendix B.

The objectives of the CQAM are:

- (1) To establish policies that assure the quality of services and data provided is adequate to support the NRC during the licensing process.
- (2) To establish the Center policies relating to QA.
- (3) To provide a uniform and consistent approach to the attainment of an acceptable level of quality within available resources for products developed under the Center contract.

This QA program applies to Center activities which are important to high-level waste repository licensing. Specifically, these activities include regulatory, institutional, and technical uncertainty identification and reduction, which are accomplished through analyses, research, development, investigations, and technical assistance to the NRC. Activities of a purely administrative or fiscal nature are not within the scope of this QA program. This QA program applies to all personnel and organizations—the Center, SwRI, and Center subcontractors and consultants—performing activities affecting quality. Definitions of terms pertinent to this program are found in Appendix I.

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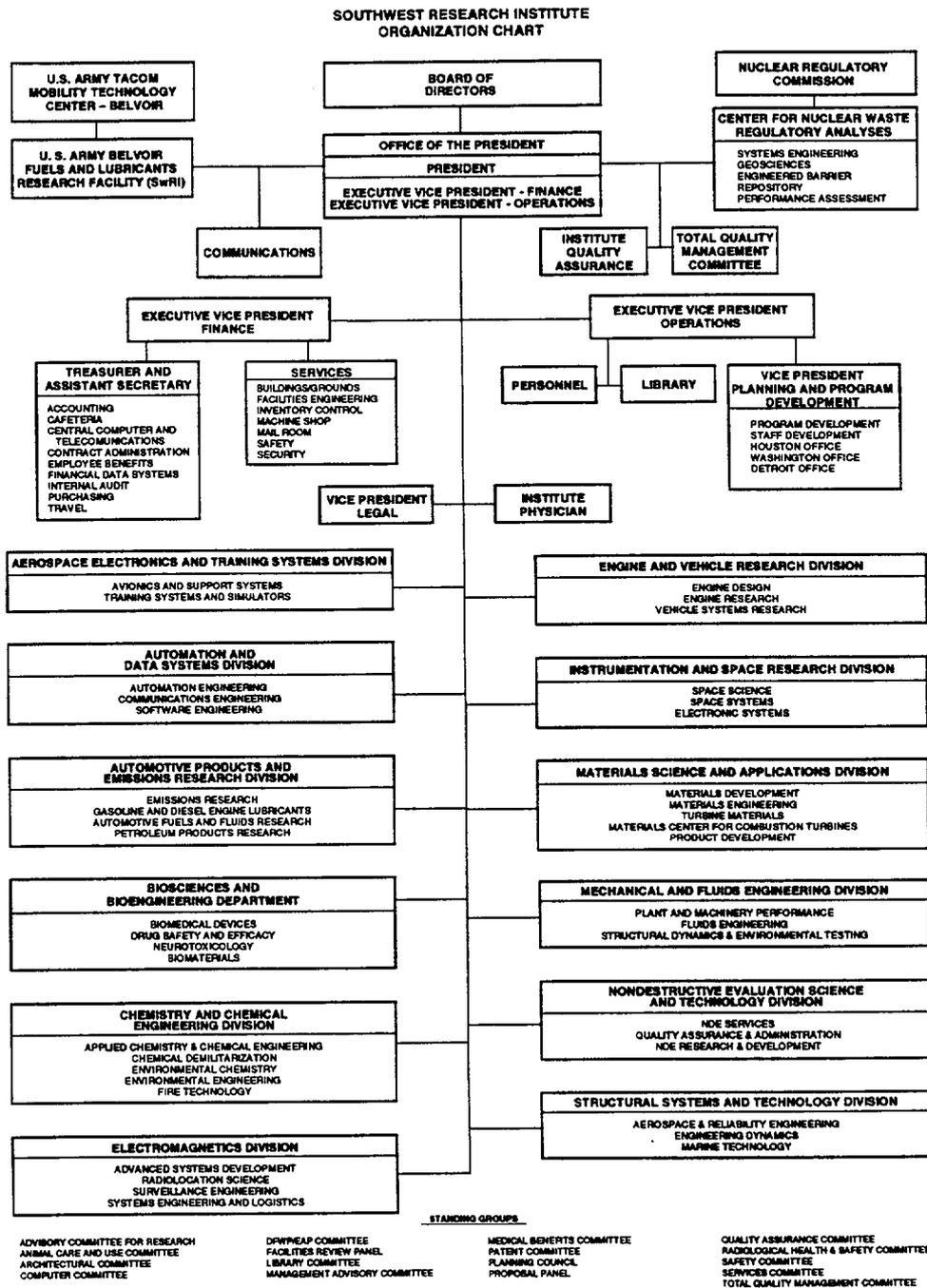


FIGURE 1.1



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Specific Center activities may utilize other accepted industry standards and practices. These shall be identified in Project Plans, Scientific Notebooks and operating procedures, when applicable. Applicable standards may include, but are not limited to:

- American Society of Mechanical Engineers Codes
- American Society for Nondestructive Testing Recommended Practice: ASNT-TC-1A
- American Society for Testing and Materials Methods and Practices
- Environmental Protection Agency methods
- Other professional society and accepted industry methods and practices

**2.3.2 Applicability of Requirements to CNWRA Activities**

- (1) This quality assurance program is applicable to CNWRA technical and regulatory analysis activities and products. It is not applicable to administrative and financial activities within the CNWRA and between the CNWRA and the NRC.
- (2) Controls applicable to specific activities are dependent upon their importance to the HLW repository license application review process. The development, acquisition, and use of data, analysis methods, and software that are expected to be used in the license application reviews shall be controlled in accordance with procedures implementing Sections 3.5, 3.9, and 3.6.1 of this CQAM. The development, acquisition, and use of data, analysis methods, and software for other uses shall follow good scientific and engineering practices and procedures implementing sections of the CQAM, as appropriate.

**2.4 STRUCTURE OF THE CNWRA QA PROGRAM**

**2.4.1 QA Program Documents**

- (1) CNWRA Quality Assurance Manual

The policies and primary programmatic controls of the CNWRA QA Program are incorporated into this CQAM. The CQAM describes the methods by which appli-

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Scientific Notebook provides sufficient detail and content so that the experimental approach may be verified and the work repeated.

**2.4.2 Control of Activities Affecting Quality**

CNWRA activities affecting quality are conducted in accordance with the CQAM and the other QA documents identified in paragraph 2.4.1. The portions of the CQAM which are applicable, the level of control, and specific controls applied depend on the type of activity and its importance, and are determined by QA and technical staff through quality planning and procedure development. Systematic Regulatory Analysis, Technical Assistance, and similar activities are controlled generally through Operations Plans, and specifically by applicable TOPs. Research projects are controlled generally through Project Plans. Quality planning activities shall be conducted to determine the specific procedures applicable to individual activities. Quality planning shall be repeated as necessary to address additional and revised tasking.

**2.5 MANAGEMENT ASSESSMENT**

**2.5.1 Internal Audits and Surveillance**

Evaluations of the effectiveness of the implementation of the CNWRA QA Program shall be scheduled by the CNWRA Director of QA. Programmatic elements and technical products are evaluated through periodic audits. Experimental and test activities shall be evaluated through timely surveillance by witnessing. Hold points shall be incorporated into planning documents as necessary to assure that verifications are accomplished.

**2.5.2 SwRI Quality Assurance Committee**

- (1) The SwRI Operating Policies and Procedures Section 1.2.9 specifies that the Quality Assurance Committee shall independently monitor and review the activi-

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ties of each SwRI QA program. Committee membership consists of representatives from each division (including the CNWRA) having QA programs. Institute and CNWRA QA management are non-voting members.

(2) Committee functions include the following:

- Recommend any actions necessary to assure the adequacy of Institute quality assurance programs.
- Serve as a review board as necessary to evaluate deficiencies and nonconformances reported by quality assurance audits and monitor corrective action programs. Assure that sufficient follow-up reviews have been made to determine that the final corrective action is timely and effective.
- Annually review the implementation of each quality assurance program and submit a written report of findings.

**2.6 INDOCTRINATION, TRAINING AND QUALIFICATION**

**2.6.1 QA Program Indoctrination and Training**

(1) CNWRA technical staff, key SwRI personnel, and contractor/consultant personnel performing activities affecting quality shall receive indoctrination and training to familiarize them with the CNWRA QA program and its implementation. Instruction shall, as a minimum, cover the following topics:

- CNWRA and Institute policies and procedures related to QA
- Authority and duty of CNWRA personnel performing activities related to QA
- Summary of the QA program, with emphasis on how the requirements apply to Element and/or project product quality

(2) A record of indoctrination/training, program content, and related information shall be maintained by CNWRA QA. When a determination is made that follow-up QA training is necessary, the QA Director shall ensure that such training is provided.

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**3. SCIENTIFIC INVESTIGATION AND ANALYSIS CONTROL**

**3.1 PURPOSE**

The purpose of this section is to describe methods for controlling systematic regulatory analysis, technical assistance, and research activities.

**3.2 RESPONSIBILITIES**

- (1) The Technical Director is responsible for overall implementation of this section.
- (2) Directors, Element Managers, and Principal Investigators are responsible for preparing Project Plans, Operations Plans, Work Plans, Test Plans, Operating Procedures, and Scientific Notebooks implementing this section, as appropriate.

**3.3 INTRODUCTION**

Center regulatory, institutional, and technical analysis, technical assistance, and research activities shall be planned, accomplished, and verified under controlled conditions.

**3.3.1 Systematic Regulatory Analysis**

Systematic Regulatory Analysis and similar activities are identified in Operations Plans, which provide objectives, general task descriptions, and project management and cost information.

Recurring activities shall be controlled through the development and implementation of Technical Operating Procedures (TOPs). For some tasks, prior knowledge of the specific analysis method is impossible, and the method is developed and enhanced as a consequence of performing the analysis itself. In these cases, TOPs shall be drafted, personnel trained as necessary to the draft procedures, and the analysis methods shall be finalized through successive modifications to the draft procedures. Once the procedures are finalized, formally approved and distributed, the work performed during development shall be evaluated and may be accepted based on verification of compliance to the finalized, formally approved procedures.

SRA products shall be loaded for retrieval and compilation into derivative reports in the Regulatory Program Database (RPD). Controls shall be provided (i) to verify proper loading of SRA products into the database, (ii) to assure that only the latest re-

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vision of the SRA products in the database are available for review and report development, and (iii) to control changes to the SRA products in the database.

**3.3.2 Technical Assistance and Research**

Project Plans and Operations Plans provide for planning and general control of technical activities, which may include literature searches, design of experiments, experiments and tests, data analysis and computer model analysis. Plans identify the technical objectives, describe each task of the technical program, describe the program management, and identify the portions of this CQAM section applicable to the activities.

Scientific Notebooks are utilized to plan and control technical tasks. Since the specific direction of a technical activity usually depends on the outcome of preceding activities, the exact method cannot be planned in advance. The Scientific Notebook documents the decision paths leading to performance of an activity and also identifies the method used, provides for quality verification, and documents the results. The Scientific Notebook provides adequate controls of activities affecting quality while allowing flexibility and adaptability for developmental and experimental technical activities.

**3.4 LITERATURE SEARCHES**

- (1) Operations Plans and Project Plans shall identify the individual(s) responsible for literature search tasks, based on the qualifications required to perform the task.
- (2) The results of a literature search shall be documented and shall receive a technical review in accordance with applicable operating procedures.

**3.5 CONTROL OF EXISTING DATA**

- (1) Quality planning (see Section 2.4.2) shall identify tasks in which existing data, collected without required quality assurance program controls, may be used for interpretation or analysis. Existing data which will not be used to support conclusions affecting licensing support activities are not subject to qualification.
- (2) Existing data qualification shall be accomplished by peer review, use of corroborating data, use of confirmatory testing, or collection under an equivalent QA program, under

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the guidelines of NUREG-1298, "Qualification of Existing Data for High Level Waste Repositories."

**3.6 DEVELOPMENT, USE, AND EVALUATION OF SOFTWARE**

**3.6.1 Scientific and Engineering Software**

Scientific and Engineering Software (i.e., software that contain mathematical or numerical models of physical processes or configurations) will be developed, modified, and evaluated as part of CNWRA task activities. Software that is expected to be utilized in evaluating the DOE's license application (i.e., software identified in NRC's License Application Review Plan review methods) shall be controlled to assure that (i) the specific configuration of a code used in analysis is identifiable and traceable to the necessary software documentation, and (ii) the code has been demonstrated to correctly implement its mathematical or numerical model (code verification and validation). Control of affected software shall be consistent with the guidance of NUREG/BR-0167.

CNWRA management shall identify the computer codes that are expected to be used in the license application review and shall determine the schedules for placing them under control.

**3.6.2 Regulatory Program Database Computer Code**

The Regulatory Program Database (RPD) computer code shall be controlled to assure accurate control of the RPD contents and its derivative reports. Documentation, to include a functional description of the code and user's manual, shall be developed. The code shall be tested to verify its proper operation, and the test methods and results shall be documented. Versions of the RPD code shall be uniquely identified. Prior to implementation and use of a new version of the RPD code, the required documentation shall be revised as necessary, and the code shall be retested.

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3.7 CONTROL OF EXPERIMENTS AND TESTS

3.7.1 Design of Experiments

Statistical design of experiments, when utilized for research projects, shall be described in Project Plans or documented in Scientific Notebooks. Documentation of design of experiments shall be sufficient so that an independent, technically qualified individual may verify methods, approaches, sample sizes, and other critical experimental design parameters without recourse to the originator.

3.7.2 Control by Scientific Notebook Method

Technical activities are primarily controlled by Scientific Notebooks. The Principal Investigator for the task shall develop and maintain the Scientific Notebook as specified in CNWRA Operating Procedures. Notebook issuance shall be controlled in accordance with CQAM Section 6. The Scientific Notebook provides historical documentation of the activity including planning, conduct of the activity, and documentation of results.

3.7.3 Control by Technical Operating Procedures

Detailed Technical Operating Procedures (TOPs) should be used whenever the work is repetitive. Such TOPs shall be developed in accordance with the requirements given in CQAM Section 5.

3.7.4 Nonconformances

Nonconformances to Operations Plans, Project Plans, Operating Procedures, Scientific Notebooks, and other work instructions shall be identified, controlled and reported in accordance with CQAM Section 15.

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3.8 VERIFICATION OF EXPERIMENTS AND TESTS

Periodic surveillance of technical activities shall be conducted to verify compliance with applicable procedural requirements. The surveillance shall include, as appropriate, direct witnessing of experiment and test events and shall include review of the Scientific Notebook for required entries and documentation.

3.9 DATA INTERPRETATION AND ANALYSIS

- (1) Interpretation and analysis, including systematic regulatory analysis and scientific investigation data interpretation and analysis, shall be performed in a planned, controlled, and documented manner. Interpretation/analysis shall be performed and documented in sufficient detail as to purpose, method, assumptions, input, references, and units such that a technically qualified person may review, understand, and verify the analysis without recourse to the originator. Scientific notebooks (in Section 3.7.2) shall be utilized to document these activities.
- (2) Calculations, including data reduction, statistical analysis, and routine scientific and engineering calculations, shall be documented and verifiable. Documentation shall be sufficient to identify the data inputs and their sources and the calculation formula or algorithm such that calculations may be replicated.

Software may be utilized for routine calculations without individual verification of the program for each application provided that a) the computer program has been verified to show that it produces correct solutions for the encoded algorithm within defined limits for each parameter employed, and b) the encoded algorithm is appropriate for the particular application.

3.10 REVIEWS

Technical products of the CNWRA, including reports, papers, and presentations, shall receive appropriate technical or peer reviews. Peer reviews shall be conducted in accordance with operating procedures addressing the guidelines of NUREG-1297, "Peer Review for High-Level Nuclear Waste Repositories." In addition to technical/peer reviews, products shall receive programmatic reviews to verify that CNWRA contractual requirements, objectives, and programmatic requirements are correctly and consistently addressed.

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3.11 REFERENCE DOCUMENTS

U.S. NRC, "Qualification of Existing Data for High-Level Waste Repositories," NUREG-1298 (February 1988).

U.S. NRC, "Peer Review for High-Level Nuclear Waste Repositories," NUREG-1297 (February 1988).

U.S. NRC, "Software Quality Assurance Program and Guidelines," NUREG/BR-0167 (February 1993).

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**7.4.2 Procurement Document Review**

- (1) Purchase documents shall be reviewed by the cognizant CNWRA Element Manager to verify that appropriate provisions are included to assure that the items or services will meet the specified requirements.
- (2) For purchases to be obtained from, or requiring qualified suppliers, the Director of QA shall review purchase documents to verify that the appropriate quality requirements are included, such as application of the supplier's approved QA program to the purchase, documentation requirements, and controls for nonconformances.
- (3) Procurement document changes to the scope of work, quality, or technical requirements shall be approved in the same manner as originals.

**7.5 SUPPLIER SELECTION AND QUALIFICATION**

**7.5.1 Commercial Grade Procurement**

Commercial grade items, materials, and equipment shall be purchased from either:

- (a) Suppliers qualified in accordance with paragraph 7.5.2 and accepted in accordance with paragraph 7.6.1(1).
- (b) Any (non-qualified) supplier and accepted in accordance with paragraph 7.6.1(2).

**7.5.2 Qualified Suppliers**

- (1) Supplier qualification shall be based on one or more of the following criteria:
  - (a) Documented history of providing identical or similar products meeting the technical requirements of the procurement documents. Non-qualified suppliers of commercial grade items may be upgraded to qualified suppliers by demonstrating consistent conformance to technical requirements.

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- (2) Laboratory chemicals and reagents utilized as analytical standards shall be selected based on the purity and concentration accuracy requirements of the analysis to be performed. Chemical and reagent grades shall meet industry practices for purity and concentration accuracy.

**12.6 CALIBRATION PROCEDURES**

- (1) Equipment and standards subject to scheduled recalibration shall be calibrated in accordance with documented TOPs or instructions. Manufacturers' and industry standard methods may be used so long as sufficient details are provided by the method.
- (2) Calibration procedures shall provide a description of the method to be used, accuracy requirements for standards, and accuracy requirements of the item being calibrated.
- (3) Calibrations before use shall be performed in accordance with documented procedures or instructions when available. When not available, methods used shall be documented in the Scientific Notebook.

**12.7 OUT-OF-TOLERANCE EVALUATIONS**

- (1) Whenever an item of measuring or test equipment is found out of tolerance, a nonconformance report shall be initiated in accordance with CQAM Section 15. An evaluation of the out-of-tolerance condition shall be made to determine if measurements made since the last valid calibration were adversely impacted.
- (2) A nonscheduled calibration shall be performed when the accuracy of an item of test or inspection equipment is in question. Measuring and test equipment found consistently to be out of calibration shall be repaired or removed from service.

**12.8 PERSONNEL QUALIFICATION**

Personnel performing calibration activities shall be qualified in accordance with CQAM Section 2 or the SwRI Nuclear Quality Assurance Program Manual.