CEMP-RT Engineer Regulation 1110-1-263	Department of the Army U.S. Army Corps of Engineers Washington, DC 20314-1000	ER 1110-1-263 30 April 1998
	Engineering and Design CHEMICAL DATA QUALITY MANAGEMENT FOR HAZARDOUS, TOXIC, RADIOACTIVE WASTE REMEDIAL ACTIVITITES	
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DEPARTMENT OF THE ARMY
U. S. Army Corps of Engineers
Washington, DC 20314-1000

CEMP-RT

ER 1110-1-263

30 April 1998

Regulation
No. 1110-1-263

Engineering and Design
CHEMICAL DATA QUALITY MANAGEMENT FOR
HAZARDOUS, TOXIC, RADIOACTIVE WASTE REMEDIAL ACTIVITIES

1. Purpose. This regulation prescribes Chemical Data Quality Management (CDQM) responsibilities and procedures for projects involving hazardous, toxic and/or radioactive waste (HTRW) materials. Its purpose is to assure that the analytical data meet project data quality objectives. This is the umbrella regulation that defines CDQM activities and integrates all of the other U.S. Army Corps of Engineers (USACE) guidance on environmental data quality management.

2. Applicability. This regulation applies to all USACE commands having responsibility for HTRW projects, within the 50 United States of America and its territories.

3. References. References are provided in Appendix A.

4. Distribution Statement. Approved for public release, distribution unlimited.

5. Acronyms. A list of acronyms is provided in Appendix B.

6. Definitions. A list of definitions is provided in Appendix C.

7. Policy. The policy of the USACE is to produce products and services which fully meet customers' expectations of quality, timeliness and cost effectiveness, within the bounds of legal responsibility. An acceptable level of quality does not imply perfection; however, there should be no compromise of

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This regulation supersedes ER 1110-1-263 dated 1 April 1996.

functional, health, or safety requirements. Adherence to the Quality Management principles outlined in Engineer Regulation (ER) 1110-1-12 will contribute to achieving this goal. CDQM procedures must be formulated to ensure harmony with the USACE Strategic Vision and should be executed in concert with activities presented in other USACE guidance.

8. Discussion.

a. The intent of this regulation is to direct CDQM to ensure the production of high quality chemical data that satisfy the project-specific data quality objectives (DQOs). This document provides policy to ensure that data are of known and appropriate quality. Detailed technical guidance on CDQM is provided in EM 200-1-6.

b. This ER allows the technical team flexibility to design a comprehensive and multifaceted approach to CDQM that is appropriate for each project. However, three requirements cannot be waived under any circumstances: (1) use of the technical project planning process culminating in project-specific DQOs; (2) use of analytical service providers with verifiable quality systems compliant with the principles of ISO/IEC Guide 25; and (3) program and project execution in accordance with the requirements of ANSI/ASQC E4.

c. The goal is to generate data of known quality for the intended usage on the first attempt. Most important is the application of guidance contained in EM 200-1-1 on laboratory validation, EM 200-1-2 on technical project planning, EM 200-1-3 on preparation of sampling and analysis plans, and EM 200-1-6 on chemical quality assurance.

d. To effectively and efficiently deliver quality products and services, on time and within budget, the project manager (PM) must control the project resources planned and budgeted. When the USACE accepts a project, the PM is ultimately responsible for the quality of the project. A district project chemist must be involved in project CDQM support. However, execution of the

USACE CDQM program may involve a variety of staff, including center or region chemists, Chemistry Quality Assurance Branch (CQAB) chemists, HTRW Center of Expertise (CX) chemists, HQUSACE chemist, and geographic district engineering and construction personnel. As outlined in ER 5-1-11, the PM not only leads the team, but is also responsible for directing it to ensure the products and services of the team meet the quality expectations, and cost/schedule commitments made to the customer.

e. This ER describes a comprehensive Quality Assurance (QA) program to monitor compliance. These procedures may also apply to in-house projects. The district project chemist, in conjunction with the technical team, shall determine the appropriate level of compliance monitoring. This determination shall be based upon the intended use of the results and the degree of confidence needed in the quality of the results. The required level of compliance monitoring shall be included in the project DQOs. Compliance monitoring may consist of a combination of activities, which are fully described in EM 200-1-6. Compliance monitoring activities include: (1) validation of primary and QA laboratories; (2) technical document review; (3) sample handling quality assurance; (4) quality assurance sample collection and analysis; (5) data review in the form of a Chemical Quality Assurance Report(CQAR); (6) assessment of data usability in the form of a Chemical Quality Data Assessment Report(CDQAR); (7) single-or double-blind performance evaluation sample analysis;(8) review of primary laboratory data; (9) validation of data; (10) field audits; (11) laboratory audits; and (12) tape audits.

f. While all twelve of these CDQM activities may be used, six of the twelve should be used on most projects. The six primary CDQM activities for USACE HTRW projects are validation of primary and QA laboratories; technical document review; sample handling quality assurance; QA sample collection and analysis; preparation of CQARs; and preparation of CDQARs. These compliance monitoring procedures should routinely be considered as candidates for inclusion in each project's set of CDQM activities.

g. Any of these six primary CDQM activities may be waived for a specific project by the district PM in concurrence with the technical team as defined in EM 200-1-2. Waiver of any element must be fully justified and documented in a memorandum for record (MFR). The MFR must describe how chemical data quality is preserved in the absence of the waived elements. The completed MFR must have the concurrence of the technical project team, including the district project chemist. Districts with insufficient staff chemist resources to provide technical team support shall rely upon the HTRW design district, CQAB professional staff, or the HTRW CX for chemistry support.

9. Responsibilities.

a. The Policy and Technology Branch, Environmental Division, Directorate of Military Programs, HQUSACE (CEMP-RT), is responsible for: (1) the CDQM system; (2) administering policy oversight and (3) USACE HTRW chemistry policy dissemination and implementation.

b. The HTRW CX is responsible for: (1) administering the USACE Laboratory Validation Program; (2) approving all applicable program standard operating procedures; (3) providing chemistry technical support to the HTRW program; (4) reviewing chemistry portions of selected technical documents; (5) monitoring CQARs and CDQARs; (6) providing feedback to CEMP-RT; (7) supporting CEMP-RT in USACE HTRW chemistry guidance development and dissemination; and (8) administering the performance evaluation sample program.

c. The Major Subordinate Commands(MSCs) are responsible for: (1) ensuring their assigned districts are adhering to USACE HTRW CDQM policy;(2) administering policy oversight; (3) providing feedback to CEMP-RT; and (4) ensuring corrective action for nonconformance situations in their assigned districts.

d. The districts are responsible for: (1) determining requirements for sampling and analysis; (2) project planning to ensure data quality; (3) obtaining data of known quality through

the use of validated laboratories; (4) developing project-specific DQOs and providing a DQO summary to all project laboratories; (5) performing data review to determine data quality; (6) assessing data usability in the form of a CDQAR or equivalent; (7) performing contractor oversight; (8) performing contract management; (9) submitting corrective action feedback to controlling major subordinate command (MSC); (10) providing feedback through the MSC to HQUSACE on HTRW chemistry policy and guidance; and (11) performing project management.

e. The CQAB is responsible to provide support at the request of the districts, the HTRW CX, and HQUSACE. Project services which are available include: (1) technical assistance in development of DQOs, Sampling and Analysis Plans, and commercial laboratory standard operating procedures; (2) inspecting QA sample shipments and reporting deficiencies; (3) analyzing QA samples, or providing for the analysis of QA samples; and (4) providing an independent assessment of the inter-laboratory analytical data in the form of a CQAR or equivalent, including resolution of discrepancies with the primary laboratory. CQAB may also provide technical assessment of guidance documents and support to the Laboratory Validation Program, as needed.

10. Audits. To assure that the substantive requirements of this regulation are met, the MSCs will conduct technical system audits. Audits will be conducted on the CQAB, centers and design districts, by the next higher HQ in their respective chains of command. A memorandum outlining findings will be prepared by the MSC and provided to CEMP-RT and the visited entity. A corrective action plan that describes remedies for all significant deficiencies identified in the MSC findings memorandum is mandatory. The corrective action plan shall be prepared by the audited entity and submitted to the MSC. The MSC will provide a copy of the corrective action plan to CEMP-RT.

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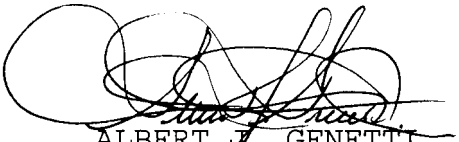
FOR THE COMMANDER:



ALBERT J. GENETTI, JR
Major General, USA
Chief of Staff

3 Appendices:
APP A - References
APP B - Acronyms
APP C - Definitions

APPENDIX A

REFERENCES

AR 5-1, Army Management Philosophy

AR 11-2, Management Control

AR 200-1, Environmental Protection and Enhancement

AR 200-2, Environmental Effects of Army Actions

AR 200-3, Natural Resources-Land, Forest and Wildlife Management

AR 600-100, Army Leadership

DA PAM 200-1, Handbook for Environmental Impact Analysis

ER 5-1-10, Corps-wide Areas of Work Responsibility

ER 5-1-11, Program and Project Management

ER 10-1-2, U.S. Army Corps of Engineers Division and District Offices

ER 385-1-92, Safety and Occupational Health Document Requirements for HTRW and OEW Activities

ER 1110-1-12, Quality Management

ER 1110-1-8158, Corps-Wide Centers of Expertise Program

ER 1180-1-6, Construction Quality Management

EM 200-1-1, Validation of Analytical Chemistry Laboratories

EM 200-1-2, Technical Project Planning Guidance for HTRW Data Quality Design

EM 200-1-3, Requirements for the Preparation of Sampling and Analysis Plans

EM 200-1-6, Chemical Quality Assurance for HTRW Projects

EM 1110-1-502, Technical Guidelines for Hazardous and Toxic Waste Treatment and Cleanup Activities

OM 10-1-2, Organization Titles

"Leadership for Total Army Quality" Concept Plan, February 1993, OCSA, HQDA (DACS-DMC-PQ)

"Environmental Cleanup and Protection Management Plan for Military Programs", January 1996, CEMP-RT

“Changes in HTRW Technical Roles and Responsibilities due to Division Laboratory Closures”, September 1997, CEMP-RT

EPA Implementation Guide for the Code of Environmental Management Principles for Federal Agencies (CEMP), EPA-315-B-97-001

ANSI Specification and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs, ANSI/ASQC E4.

ISO/IEC Guide 25 General Requirements for the Competence of Calibration and Testing Laboratories

APPENDIX B

ACRONYMS

ANSI American National Standards Institute

AR Army Regulation

ASQ American Society for Quality (formerly American Society for Quality Control (ASQC))

CEMP-RT Corps of Engineers, Environmental Division, Policy and Technology Branch

CDQAR Chemical Data Quality Assessment Report

CDQM Chemical Data Quality Management

CQAB Chemistry Quality Assurance Branch (formerly the Missouri River Laboratory, Omaha, NE)

CQAR Chemical Quality Assurance Report

CX Center of Expertise

DACS Department of the Army, Chief of Staff

DMC-PQ Director of the Army, Management Directorate, Management Practices Branch, Total Army Quality

DOD Department of Defense

DQO Data Quality Objectives

EM Engineer Manual

ER Engineer Regulation

HQUSACE Headquarters, U.S. Army Corps of Engineers

HQDA	Headquarters, Department of the Army
HTRW	Hazardous, Toxic, and Radioactive Waste
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
MFR	Memorandum for Record
MSC	Major Subordinate Command
OCSA	Office Chief of Staff, Army
OE	Ordnance and Explosives (formerly Ordnance and Explosive Waste (OEW))
OM	Office Memorandum
PM	Project Manager
QA	Quality Assurance
QC	Quality Control
USACE	United States Army Corps of Engineers
USEPA	United States Environmental Protection Agency

APPENDIX C

DEFINITIONS

Activity. An all-inclusive term describing a specific set of operations or related tasks to be performed, either serially or in parallel, that in total result in the completion of a product or service.

Assessment. The evaluation process used to measure the performance or effectiveness of a system and its elements.

Audit. An independent, systematic examination to determine whether activities comply with planned arrangements, whether the arrangements are implemented effectively, and whether the results are suitable to achieve objectives.

Center. A command and control entity similar in function to an MSC, with responsibility for a more narrowly defined scope of activities. Centers usually have programmatic and functional boundaries instead of geographical boundaries like divisions.

Characteristic. Any property or attribute of a datum, item, process, or service that is distinct, describable and/or measurable.

Comparability. A quantitative characteristic that defines the extent to which a chemical parameter measurement is consistent with, and may be compared to, values from other sampling events.

Completeness. A quantitative evaluation of what percentage of the chemical measurements met the project data quality objectives.

Conformance. An affirmative indication or judgement that a product or service has met the requirements of the relevant

specifications, contract, or regulation.

Corrective action. Measures taken to rectify conditions adverse to quality and, where possible, to preclude their recurrence.

Data of known quality. Data that have the qualitative and quantitative components associated with their derivation documented appropriately for their intended use, and such documentation is verifiable and defensible.

Data quality assessment. A statistical and scientific evaluation of the data set to determine the validity and performance of the data collection design and statistical test, and the adequacy of the data set for its intended use.

Data quality objectives. Qualitative and quantitative statements that clarify technical and quality objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed for support decisions.

Data usability review. The process of ensuring or determining whether the quality of the data produced meets the intended use of the data.

Deficiency. An unauthorized deviation from approved procedures or practices, or a defect in an item.

District project chemist. Chemist that provides project support at the district level. This should be a district chemist, or if requested by a district with insufficient resources, may be a chemist from another design district, the CQAB, or the HTRW CX.

Document. Any written or pictorial information describing,

defining, specifying, reporting, or certifying activities, requirements, procedures, or results.

Entity. Something which can be individually described and considered, such as a process, product, item, organization, or combination thereof.

Feedback. Communication of data quality performance to sources which can take appropriate action.

Finding. An assessment conclusion that identifies a condition having a significant effect on an item or activity. An assessment finding may be positive or negative, and is normally accompanied by specific examples of the observed condition.

HTRW activities. Activities undertaken for the U.S. EPA's Superfund Program, the Defense Environmental Restoration Program, including Formerly Used Defense Sites and Installation Restoration Program sites at active DOD facilities, HTRW actions associated with Civil Works projects, and any other mission or non-mission work performed for others at HTRW sites. Such activities include, but are not limited to, Preliminary Assessments/Site Inspections, Remedial Investigations, Feasibility Studies, Engineering Evaluation/Cost Analyses, Resource Conservation and Recovery Act Facility Investigations/Corrective Measures Studies/Corrective Measures Implementation/Closure Plans/Part B Permits, or any other investigations, design activities, or remedial construction at known, suspected, or potential HTRW sites. HTRW activities also include those conducted at petroleum tank sites and construction sites containing HTRW.

Independent assessment. An assessment performed by a qualified individual, group, or organization that is not a part of the organization directly performing and accountable for the work being assessed.

Inspection. Examination or measurement of an item or activity to verify conformance to specific requirements.

Item. An all-inclusive term used in place of the following: appurtenance, facility, sample, assembly, component, equipment, material, module, part, product, structure, subassembly, subsystem, system, unit, documented concepts, or data.

Manager. Individual directly responsible and accountable for planning, implementing, and assessing work.

Management system. A structured non-technical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and for producing items and services.

Method. A body of procedures and techniques for performing an activity systematically presented in the order in which they are to be executed.

Nonconformance. A deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate; nonfulfillment of a specified requirement.

Primary laboratory. Laboratory that analyzes the majority of the project samples.

Procedure. A specified way to perform an activity.

Process. A set of interrelated resources and activities which transforms inputs into outputs.

Program. A group of projects, services or other activities that may be categorized by funding source, customer requirements or other common criteria for which resources are allocated and

collectively managed.

Project. Any work (products, services, *etc.*) intended to produce a specific outcome or solution to a customer problem or need.

Project manager. The leader of the project team, responsible for managing the project parameters (budget, cost, safety, schedule, scope and quality), as well as interfacing with those involved in the project process (customers, functional elements, government, and non-government entities).

Quality. The totality of features and characteristics of a product or service that bear on its ability to meet the stated or implied needs and expectations of the user.

Quality assurance. An integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement that measures the degree of excellence of environmental data and communicates this information to a data generator or data user in a convincing manner.

Quality assurance laboratory. The CQAB or other laboratory that analyzes the project QA samples.

Quality assurance sample. A sample collected to monitor the quality of sampling operations. This type of sample is analyzed by the quality assurance laboratory and typically includes split samples, duplicate samples, and various types of blank samples.

Quality control. The overall system of technical activities that monitors the degree of excellence of environmental data so that the stated requirements of defined standards are achieved.

Quality control sample. A sample collected to monitor and control the quality of sampling operations. This type of sample

is analyzed by the primary laboratory and typically includes split samples, duplicate samples, and various types of blank samples.

Quality improvement. A management program for improving the quality of operations.

Quality management. The aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systemic activities pertaining to the quality system.

Quality system. A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products, items, and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC.

Standard operating procedure. A written document that details the process for an operation, analysis, or action, with thoroughly prescribed techniques and steps, and that is officially approved as the method for performing certain routine or repetitive tasks.

Technical review. A documented critical review of work that has been performed within the state-of-the-art. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work, but are collectively equivalent in technical expertise to those who performed the original work. The review is an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that

established requirements are satisfied.

Technical systems audit. A thorough, systematic, on-site, qualitative audit of facilities, equipment, personnel, training, procedures, record keeping, data verification/validation, data management, and reporting aspects of a system.

Validation. Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled.