

NUCLEAR WASTE MANAGEMENT PROGRAM

CONTROLLED COPY NO. 83

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033-NWMP-R 19.0	Software Quality Assurance	12/24/86	APPROVED	0
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033-NWMP-P 19.3 (EQ3/6)	Acquisition and Evaluation of Computer Codes	10/25/86	ISSUED	0
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033-NWMP-R 21A.0	Training	12/24/86	APPROVED	0
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033-NWMP-P 22.0	Technical Review of Publications	3/13/87	APPROVED	0
033-NWMP-P 22.0	Instructional Memorandum #22-1	10/4/87	ISSUED	0

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TERMS AND DEFINITION

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Acceptance Criteria: Specified limits defined in codes, standards, or other requirement documents placed on characteristics of an item, process, or service.

Account Manager: Member of the Nuclear Waste Management Program with authorization to sign on program accounts.

Activities That Affect Quality: Activities that have impact on the validity of information or data reported to NNWSI Project participants or to agencies designated to receive Project output on functions of structures, systems, or components that are important to operator safety and that could cause undue risk to the health or safety of the public. These activities may include planning, researching, developing, demonstrating, investigating, characterizing, designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, modifying, decontaminating, decommissioning, dismantling, etc.

Activity: Any work, including, but not limited to, procurements, scientific investigations, or designs that is directed toward the achievement of the objectives stated in the WBS Dictionary.

AP - NNWSI Administrative Procedure: An implementing procedure which identifies the interface control methods to meet QA requirements. The control methods are those which govern Project-wide systems and are implemented by all project participants.

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, codes, standards, instructions, drawings, and other applicable requirements, and the effectiveness of implementation.

Barrier: Any material, structure, system, or component that prevents or substantially delays the movements of water or radionuclides.

Certificate of Conformance: A document signed by an authorized individual that certifies the degree to which items or services meet specified requirements.

Certification: The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.

Characteristic: Any property or attribute of an item, process, or service that is distinct, describable, and measurable.

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Commercial Grade Item: Items ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description.

Condition Adverse To Quality: An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one which, if not corrected, could have a serious effect on safety or operability.

Containment: The confinement of radioactive waste within a designated boundary.

Containment, Period Of: Known as the period during the first several hundred years following permanent closure of the geologic repository in which radiation and thermal levels are high and the uncertainties of ensuring repository performance are great. During this time, special emphasis is placed upon the ability to contain the wastes by waste packages within an engineered barrier system.

Controlled Document: Document that prescribes an activity that has been assigned a Level of Quality Assurance I or II or that has been designated as controlled in accordance with the QAPP or by a member of the NWMP. Controlled documents include documents that assure technical adequacy, documents containing or specifying quality requirements, and documents that prescribe activities affecting quality.

Contractor: An organization under contract to provide supplies, construction, or services.

Corrective Action: The steps required to rectify a nonconforming item, procedural nonconformance, condition adverse to quality, audit finding, surveillance finding, or a nonconformance associated with a procurement action.

Corroborative Data: Information that may or may not have been acquired and controlled in a manner consistent with Quality Assurance Level I requirements and may be used as background, or corroborative support to primary data.

Design: The act of developing designs for construction or of analyzing the performance of repository engineered structures, systems, components, and natural barriers. Design documentation includes, but is not limited to, drawings, specifications, test plans, design reports, test reports, system design descriptions, configuration status listing, design manuals, and manuals describing computer programs used for design or performance analysis.

Design Input: Those criteria, parameters, bases, or other design requirements upon which the detailed final design is based.

Design Output: Documents, such as drawings, specifications, and others that define technical requirements of structures, systems, and components.

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Design Process: Technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents.

Deviation: A departure from specified requirements.

Disposition: The action taken to resolve a nonconforming condition and to restore acceptable conditions.

Document: Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a Quality Assurance Record until it satisfies the definition of a Quality Assurance Record as defined in this Section.

DOE: The U.S. Department of Energy or its duly authorized representatives.

Drawings: Pictorial representations of a configuration, including documented sketches, photographs or other forms.

Engineered Barrier System: The waste package and the underground facility.

Exempt Activity: An exempt activity is one that need not comply with the requirements specified in the procurement control and documentation procedure. All administrative activities are exempt activities.

Experiment: An attempt at discovering a causal relationship. Successful experiments are those which establish a relationship. Success is a function of the experimenter's knowledge, experience, ingenuity and perseverance. All experiments are always Level of Quality Assurance III.

External Audit: An audit of those portions of another organization's QA program that is neither under the direct control nor within the organizational structure for the auditing organization.

External Organization: An organization other than LLNL and LLNL subcontractors participating in DOE-directed nuclear waste-related activities.

Final Design: Approved design output documents and approved changes thereto.

Finding: A discovered inadequacy or noncompliance with established procedures, instructions, drawings or other applicable documents.

Functional Characteristics: Those attributes of a repository or its structures, systems, and components that determine its performance with respect to safety, reliability, operability, and other design criteria established in the OGR Program or other Federal regulatory documents.

Important To Safety: As it applies to structures, systems, and components, those engineered structures, systems, and components that are essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area at any time until the completion of permanent closure.

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Important To Waste Isolation: The barriers that must meet the criteria that address long-term performance of the engineered and natural barriers to prevent the release of radionuclides from the site to the accessible environment.

Indexing: Making a guide to facilitate reference to records by extracting information about records from the records themselves, and listing it in a convenient format.

Inspector: A person who performs inspection activities to verify whether or not an item or activity conforms to specified requirements.

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

Instructions: Written direction or guidance to assist in the accomplishment of an activity. An instruction may direct the initiation of a series of procedures and/or actions. Instructions are issued for one-time use only and are specific to an activity or an individual.

Internal Audit: An audit of those portions of an organization's QA program that is retained under its direct control and within its organizational structure.

Isolation: Inhibiting the transport of radioactive materials so that amounts and concentrations of this material entering the accessible environment will be kept within prescribed limits.

Item: An all-inclusive term that is used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, service, structure, subassembly, subsystem, system, unit, data, and prototype hardware. This term includes magnetic media, and other materials that retain or support data.

Lifetime Records: Quality Assurance Records that furnish evidence of the quality and completeness of data, items, and activities affecting quality. All NNWSI Project QA Records are classified as Lifetime Records.

Major Change: Any change other than those defined as minor changes.

MASSF: Microfilm and Archival Storage Service Facility located in Mercury, Nevada and operated by Holmes and Narver, Inc. for the NNWSI Project.

Material: A term that includes items plus any hardware or geologic samples either used in or resulting from research and development or site investigations on the NNWSI Project. Hardware and geologic specimens include but are not limited to test apparatus or equipment, special nuclear material, cores, geologic samples, water and gas samples, etc.

Measuring and Test Equipment: Devices or systems used to calibrate, measure, gage, test, or inspect, in order to control or to acquire data so that conformance to specified requirements can be verified.

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Minor Change: Any editorial or grammatical correction that does not change the intent of a document.

NNWSI Project Participants: An all inclusive term used to describe (generically) the various organizations involved in the NNWSI Project. This term includes the WMP0, Participating Organizations, and NTS Support Contractors.

NNWSI Project Personnel: All U.S. Department of Energy Participating Organizations, and NTS Support Contractor personnel involved in NNWSI Project activities.

Nonconformance: A deficiency in characteristics documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

Nonconforming Item: An item that does not conform to specified requirements.

NRC: U.S. Nuclear Regulatory Commission.

NWMP: Nuclear Waste Management Program (LLNL).

NWMP-NNWSI: The part of NWMP that supports NNWSI.

Objective Evidence: Any documented statement of fact, other information, or record, either quantitative or qualitative, that pertains to the quality of an item or activity, based on observations, measurements, or tests that can be verified.

Observation: A discovered condition which, in the opinion of the auditor, may lead to a finding if uncorrected.

One-Of-A-Kind Records: Quality Assurance records that cannot be duplicated or microfilmed are considered one-of-a-kind items. Such records include, but are not limited to the following: core samples, photographic negatives, radiographic films, multi-colored maps and map overlays.

Overview: An analysis and assessment by management of the scope, status, adequacy and effectiveness of Program quality achievement and assurance activities. Overview encompasses effectiveness assessments, technical reviews, readiness reviews, audits, and surveillances, as appropriate.

Participating Organization: The government agencies external to the DOE, national laboratories and organizations participating directly in NNWSI Project activities.

Peer: A person having technical expertise in the subject matter to be reviewed at least equivalent to that needed for the original work.

Peer Review: A documented, in-depth, critical review performed by individuals who are independent of the planning document, strategy, decision, or activity being reviewed and who have technical expertise at least equivalent to that required to produce the original work.

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Performance Confirmation: The program of tests, experiments, and analyses that is conducted to evaluate the accuracy and adequacy of the information used to determine with reasonable assurance that the performance objectives for the period after permanent closure will be met.

Primary Data: Information that can be shown to have been acquired and controlled in a manner consistent with all applicable Quality Assurance Level I requirements and is necessary for the resolution of the NRC performance objectives of 10CFR60.

Principal Investigator (PI): The individual who has the technical responsibility for a particular technical task. This responsibility includes, but is not limited to, planning and cost control, the day-to-day technical direction and control of the item or activity, and the assembly of a support team to accomplish the item or activity. This term may be synonymous with task leader or project engineer depending upon the NNWSI Project Participant.

Procedural Nonconformance: Deviation from a controlled procedure, requirement, instruction, or drawing.

Procedure: An element of the Quality Assurance Program Plan which specifies how a requirement is to be accomplished or an activity is to be performed.

Process: A procedure, method, or technique followed in the execution of a scientific investigation or the design or manufacture of an engineered item.

Procurement Document: Purchase requisitions, purchase orders, letters of intent, work authorization letters, drawings, contracts, specifications, instructions, or any document that provides a means by which to acquire possession or ownership of items, or right to the use of services by payment.

Purchaser: The organization responsible for the establishment of procurement requirements and for the issuance or administration, or both, of procurement documents.

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

Qualified Procedure: An approved procedure that has been demonstrated to meet the specified requirements for its intended purpose.

Quality Assurance: All those planned and systematic actions that are necessary to provide adequate confidence that the geologic repository and its subsystems or subcomponents will perform satisfactorily in service. Quality Assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system that provide a means by which to control the quality of the material, structure, component, or system to predetermined requirements.

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Quality Assurance Administrative Procedure: A document that specifies or describes how a sponsor's quality assurance element is to be implemented. All such documents are controlled and become part of the NWMP Quality Assurance Program Plan. (Note: A QAAP is not to be confused with and "Administrative Procedure" (AP)", which is a document issued by a Sponsor.)

Quality Assurance Level I: Activities conducted and items used with the intent to provide direct support for the Department of Energy to submit a license application for a potential repository; activities and items that are radiological health and safety related, are important to either safety or waste isolation, and are associated with the ability of a nuclear waste repository to function in a manner that prevents or mitigates the consequences of a process or event that could cause undue risk to the radiological health and safety of the public.

Quality Assurance Level II: Activities and items related to systems, structures, and components that require a level of quality assurance sufficient to provide for reliability, maintainability, public nonradiological health and safety, repository worker health and safety, both radiological and nonradiological, and other operational factors that would have an impact on the DOE Project Office concerns and on the environment.

Quality Assurance Level III: Activities and items that are not assigned Level of Quality Assurance I or II.

Quality Assurance Program Plan (QAPP): The document that describes the organization's Quality Assurance Program, the applicable QA Requirements, and the instructions to implement and apply the QA requirements to activities.

Quality Assurance Record: An individual document or other item that has been executed, completed, and approved and that furnishes evidence of (1) the quality and completeness of data (including raw data), items, and activities affecting quality; (2) documents prepared and maintained to demonstrate implementation of Quality Assurance programs (e.g., audit, surveillance, and inspection reports); (3) procurement documents; (4) other documents such as plans, correspondence, documentation of telecons, specification, technical data, books, maps, papers, photographs, and data sheets; (5) items such as magnetic media; and (6) other materials that provide data and document quality regardless of the physical form or characteristic. A completed record is a document or item (and documentation) that will receive no more entries, whose revisions would normally consist of a reissue of the document (or documentation), and that is signed and dated by the originator and, as applicable, by approval personnel.

Receiving: Taking delivery of an item at a designated location.

Record: A document that will either receive no more entries or whose revisions would normally consist of the reissue of the document; and is signed and dated by the originator and, as applicable, by personnel authorized to approve the document.

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Repair: The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does not conform, to the original requirement.

Requestor: The individual originating a procurement action. If the requestor is a Task Leader or above, then that same individual has responsibility for fulfilling the responsibilities assigned to the Task Leader.

Requirement: An element of the Quality Assurance Program Plan which specifies what is to be done and who is responsible. A requirement does not specify how the requirement is to be accomplished.

Rework: The process by which a nonconforming item or activity is made to conform to the original requirements by completion or correction utilizing existing approved procedures.

Right of Access: The right of a purchaser or designated representative to enter the premises of a Supplier for the purpose of inspection, surveillance, or Quality Assurance audit.

RMS: Records Management System.

RMS Database: A proprietary indexing software package developed by Effective Solutions, Inc. for use on NNWSI Project quality assurance records. The package consists of Revelation by Cosmos, Inc. with the applications program R/Maker by DP Development. The database is used to provide a user with information on how to retrieve records submitted to the NNWSI Project Sponsor.

SANL: DOE has established a system that enables the Laboratory to obtain goods and services from DOE Weapons complex integrated contractors, other DOE prime contractors, Federal agencies, and the military. The Special materials Office of the Weapons engineering Department handles there requests. The acronym "SAN" ("San" - San Francisco Regional Office/DOE and "L" LLNL") is LLNL's identifier within this system.

Scientific Investigation: Any research, experiment, test study, or activity that is performed for the purpose of investigating the natural barriers or the man-made aspects of the geologic repository, including the overall design of the facilities and the waste package. This will include, but will not be restricted to, all geologic, tectonic, seismologic, hydrologic, climatologic, geochemical, chemical, geophysical, physical, geomechanical, mechanical, meteorological, metallurgical, environmental, socioeconomic, and transportation studies of activities which are performed for, or in support of, the investigation, exploration, site characterization, development of design bases, licensing, construction, operation, monitoring, performance evaluation and/or closure of the geologic repository.

Service: The performance of activities that include but are not limited to site characterization, design, fabrication, investigation, inspection, nondestructive examination, repair, or installation.

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Special Process: A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

Supplier: Any individual or organization under contract to provide items or services to the DOE/NV, to a Participating Organization, or to an NTS Support Contractor for NNWSI Project activities.

Surveillance: The act of monitoring or observing to verify whether or not an item or activity conforms to specified requirements.

Technical Representative: The individual assigned responsibility by the Task Leader for technical decisions related to the procurement action. The technical representative is likely to be the requestor, but need not be. The Task leader can serve as the Technical Representative.

Technical Review: A documented traceable review performed by qualified personnel who are independent of those who performed the work but who have technical expertise at least equivalent to those who performed the original work. Technical reviews are in-depth, critical reviews, analyses and evaluation of documents, material or data that require technical verification and/or validation for applicability, correctness, adequacy and completeness.

Test: Examination, investigation, evaluation and documentation of inherent properties, functionability, environmental reaction, variances, and reliability of any article, material or process.

Testing: An element of verification that is used to determine the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

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

Training: In-depth instruction provided to personnel to develop and demonstrate initial proficiency in the application of selected requirements, methods, and procedures, and to adopt to changes in technology, methods, or job responsibilities.

Use-As-Is: A disposition that is permitted for a nonconforming item or service when it can be established that the item is satisfactory for its intended use.

Verification: The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether or not items, processes, services, or documents conform to specified requirements.

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Waiver: Documented authorization to depart from specified requirements.

Waste Management Project Office (WMPO): The organization to which the U.S. Department of Energy, Nevada Operations Office (DOE/NV), has assigned the responsibility of administering and coordinating the activities of various Participating Organizations and NTS Support Contractors associated with the NNWSI Project.

Waste Package: The waste form and any containers, shielding, packing, and other absorbent materials immediately surrounding an individual waste container.

Work Breakdown Structure (WBS) Dictionary: A product-oriented framework for organizing and defining work to be accomplished.

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CONTROLLED DOCUMENT
TRANSMITTAL RECORD

5/4/88
(Transmittal date)

TO: <div style="border-bottom: 1px solid black; padding: 2px; margin: 5px 0;">J. Kennedy (Name)</div> <div style="border-bottom: 1px solid black; padding: 2px; margin: 5px 0;">NRC (Organization)</div>		FROM: <div style="border-bottom: 1px solid black; padding: 2px; margin: 5px 0;">John Dronkers (Name)</div> <div style="border-bottom: 1px solid black; padding: 2px; margin: 5px 0;">LLNL/NWMP (Organization)</div>	
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	C. Terms and Definition	7	4/28/88
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