APPENDIX A
QUALITY MANAGEMENT GUIDEBOOK:
GLOSSARY
May 1995

Acceptance - A positive inspection result that indicates full compliance with specifications, drawings, or documents containing acceptance criteria.

Acceptance Criteria - Specified limits placed on characteristics of an item, process, or service that is defined in drawings, specifications, codes, industry standards, procurement, or other design output documents (NQA-1).

Acceptance Testing -

Accuracy - A measure of the agreement between the true value and the measured value quantitatively expressed by uncertainty. The "true" value is considered to be the best obtainable value and is usually arrived at by multiple measurements of carefully constructed standard or reference materials.

Action Limits - The established measurement control values beyond which any variation indicates that approved corrective action must be implemented prior to the resumption of the use of the instrument for accountability purposes. Typically, action limits are established at the 99 percent confidence level.

As-Built Data - Documented data that describe the actual configuration or condition of an item or facility.

Assembly - A number of parts, or combination(s) thereof joined together to perform a specific function, and capable of disassembly.

Audit - A planned and documented activity performed in accordance with management or quality procedures to determine, by examination and evaluation of objective evidence, the adequacy of and extent to which applicable criteria or elements of the Organization's Program have been developed, effectively implemented, and documented (NQA-1).

Audit Team Members - Individuals who compose an audit team of one or more members, at least one of which shall be qualified as a Lead Auditor. Audit Team Members have no direct responsibility for performance or oversight of the specific activities to be audited.

Audit, external - An audit of those portions of another organization's quality assurance program not under the direct control or within the organizational structure of the auditing organization (NQA-1).

Audit, internal - An audit of those portions of an organization's quality assurance program retained under the direct control and within its organizational structure (NQA-1).

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.

Auditor - An individual who is trained and qualified to perform a portion of an audit assigned by a Lead Auditor.

Auditor-in-Training (Auditor Trainee) - An individual who should not be considered an active participant in the audit, but who is in the process of becoming qualified as an auditor.

Baseline Software. Software that has been formally reviewed and agreed upon, and that can only be changed through formal change control procedures.

Bias - A systematic error, as opposed to a random error (chance variation), in which the average value of the measurement of a quantity differs from the true value. Bias may be a positive or negative deviation from the true value.

Calibrating Organization - The organization performing the calibration of a specific item of measuring and test equipment. Usually this is the Standards Laboratory, although in some cases the user organization may perform its own calibration or verification.

Calibration - The comparison of measuring and test equipment or measurement standard of unknown accuracy to a measurement standard of known accuracy to detect, correlate, report , or eliminate by adjustment any variation if the accuracy.

Certificate of Conformance (C of C) - A document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements (NQA-1).

Certification - The act of determining, verifying, and attesting to a given action or physical characteristic by an independent party. In the context of training, certification is usually based upon the successful completion of a systematically designed training program. The act of certifying an individual is the final action within a formally documented, audible process in which the skills, knowledge, and abilities of the individual are evaluated against formal standards and attested to by an independent party (From the New Production Reactor Program, (NPR).

Characteristic - Any property or attribute of an item, process, or service that is distinct, describable, and measurable (NQA-1).

Class A Property - Includes land and improvements such as buildings, roads, fences, bridges, and the equipment installed as a part of the basic building construction.

Class B Property - Includes all items such as reactors, accelerators and related machinery, chemical processing lines, lasers, computers, machine tools, office equipment, etc. that are used for programmatic purposes. At LANL all engineering associated with the initial design and subsequent modification and maintenance is the responsibility of the operating organization.

Code - In software engineering, a set of unambiguous rules specifying the manner in which data may be represented in a discrete form..

Commercial Calibration Laboratory - A subcontractor who has been approved by LANL to perform calibrations on measurement standards and measuring and test equipment.

Commercial-Grade Item (CGI) - Items that are not subject to design or specification requirements unique to a facility; items used in applications other than at a given facility and ordered on the basis of the manufacturer's published product data, e.g., catalog (NPR).

Component - Either a part, assembly, or more usually, a combination of parts, subassemblies or assemblies, usually self contained, which perform a design function. Components may be wither hardware, software, or a combination of both.

Computer program - A sequence of instructions suitable for processing by a computer. Processing may include the use of an assembler, a compiler, an interpreter, or a translator to prepare the program for execution as well as to execute it. Computer programs covered by this Standard are those used for:

- (a) design analysis;
- (b) operations or process control; or
- (c) data base or document control registers when used as the controlled source of quality information for
- (a) or (b) above (ANSI/IEEE Standard 729-1983).

Computer Program. A set of coded instructions for representation of a physical process or system that has been written in a language suitable for compilation to a form executable on a digital computer. (NPR)

Computer System. A functional unit, consisting of one or more computers and associated software. (NPR)

Conceptual Design (Pre-Title I) - The initial phase of project engineering. The major objectives of conceptual design are to develop the project scope to satisfy mission requirements, to validate project feasibility and construct ability, to develop budget cost estimates and the funding schedule, to establish realistic project schedules, and to identify project uncertainties. The elements included in conceptual design vary with the size, cost, and complexity of the project.

Conceptual Design Report (CDR) - The CDR is used in the DOE validation stage that precedes the inclusion of a project in the annual DOE budget submittal to congress. CDRs contain construction and cost estimate detail; narratives and drawings; justifications relating to mission and program requirements, sizing, key feature requirements, and the driving element; relationships with other projects; and overall site plan and site mission objectives. Significant alternatives addressed during all phases of conceptual development are included in the CDR, along with a rationale for choosing the approach being proposed.

Concern. The status of an activity that, if continued, would cause its quality to become unacceptable or indeterminate. (NQA-1)

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 uncorrected, could have a serious effect on safety or operability (NQA-1).

Configuration Control Board (CCB) - A board that reviews and acts on design changes for submittal to a customer or incorporation into the design. The CCB consists of a chairman and designated representatives that may include Construction, Program Management, Design Agency, Materials Management, and other organizations as requested by the CCB chairman.

Configuration Control. The process of identifying and defining the configuration items in a software package, controlling the release and change of these items throughout the software life cycle, recording and reporting the status of configuration items and change requests. (NPR)

Configuration Item. A collection of hardware or software elements treated as a unit for the purpose of configuration control. (NPR)

Configuration Management (CM) - A discipline applying technical and administrative direction and surveillance to identify and document the functional and physical characteristics of a configuration item, control changes to those characteristics, record and report change processing and implementation status, and verify compliance with specified requirements.

Conformance - The character, form, or manner of an item or service being in agreement with Laboratory specifications describing the item or service.

Controlled (Receipt requested) Distribution - Documents that are identified by subject, have unique identification, typically have revision status, and are assigned to designated individuals or locations by name. Individuals must sign a receipt for documents they receive. Individuals having controlled distribution documents receive copies of all revisions for unique documents assigned to them.

Controlled Data - Data that are obtained for one or more of the following purposes:

- a. For use in reports, publications, specifications, or furnishing a product;
- b. For determining acceptability of the characteristics of processes, systems, or structures;

- c. For the accountability of nuclear materials;
- d. For security systems; and
- e. For the protection of the health and safety of personnel and the environment.

Controlled Document - A document, the preparation, issuance, and revision of which are controlled to ensure that correct instructions, procedures, drawings, or other documents are being used for specific work tasks. For the purposes of this guidebook, a controlled document is also a quality assurance record.

Controlled Document Copy. A copy of a controlled document that has been compared to the original document and verified to be correct by the Document Custodian (or designee). (NPR)

Controlled Identification - Documents that are identified by subject, have unique identification, and typically have revision status. Distribution is specific to individuals or locations by name. Documented receipt is not required.

Controlled M&TE - Measuring and test equipment that is used to obtain physical, dimensional, electrical, radiological, or chemical controlled data or to calibrate equipment used for this purpose.

Corrective Action - Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition (NQA-1).

Corrective Action Report (CAR) - A written report issued on significant deficiencies such as recurring nonconformances on the same defect, by-passed inspection hold points, or continued use of defective equipment that could jeopardize personnel safety. A CAR addresses systematic weaknesses identified by assessments, audits, or NCR tracking.

Corrective Action. Measures taken to rectify conditions adverse to quality. (NPR)

Cross-Check - The comparison of a measurement standard and/or M&TE with another of known accuracy. A cross-check can be used to determine if the calibration has degraded due to use, handling, environment, or device deterioration.

Critical - A component or activity is considered critical if failure of the component or poor execution of the activity produces one or more of the following; a significant safety incident, substantial loss of project resources. or lengthy delay of schedule.

Deficiency. A characteristic important to safety that renders the quality of an activity unacceptable or indeterminate. (NPR)

Definitive (or Final) Design (Title II) - Document(s) that completes the detailed design of the project and provides the information necessary to prepare a bid package for construction. The definitive design provides final specifications for construction and equipment procurement; detailed drawings for construction; design calculations; cost estimates to serve as a basis for the Government Cost Estimate; construction schedule; identification of permits required; and an updated Energy Conservation Report.

Design Agency - The organization responsible for Title I preliminary design and Title II definitive design. Such services may be performed in-house by the Laboratory in whole or in part, or contracted to an independent design firm or the Laboratory's support services subcontractor (SSS), depending upon the type and magnitude of the project.

Design Authority - The LANL cognizant technical organization having final technical responsibility for the item, process, or activity. The Design Authority may delegate design responsibilities to another organization, which becomes the Design Agency, or may retain the Design Agency responsibilities. When the Design Agency responsibility is delegated to other organizations, the Design Authority shall retain final technical responsibility for the item, process, or activity.

Design Change - Any revision or alteration of the technical requirements that are defined by approved and released design output documents; or approved and released changes thereto (NQA-1).

Design Criteria - Technical information developed during project identification, conceptual design, and/or preliminary design phases. Design criteria are normally consolidated into a document that provides the technical base for any further design activity. The criteria define the project scope; construction features and requirements; design parameters; applicable design codes, standards, and regulations; applicable health, safety, and fire protection safeguards; security; energy conservation; quality assurance; and other requirements.

Design Document - A drawing, specification, or other document that defines the technical requirements of items, systems, or structures.

Design Input - Those criteria, parameters, or other design requirements on which the detailed final design is based (NQA-1).

Design Output - Documents such as drawings, specifications, and other documents that define the technical requirements of items, structures, and systems (NQA-1).

Design Package - The drawings, specifications, and change documents required for the design and construction of a project or changes thereto.

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 (NQA-1).

Design Process Hazards Review (DPHR) - A systematic review of a process that identifies potential hazards; evaluates possible consequences of those hazards relative to established criteria; and prescribes actions that must be taken to prevent or mitigate the consequences.

Design Review - A deliberately critical examination and evaluation to ensure that designs, including drawings, specifications, calculations, theoretical analyses, and qualification tests, clearly, accurately, and completely describe technical requirements of the item in sufficient detail for the appropriate design phase.

Design Review Board (DRB) - An interdisciplinary design team that reviews a project design (or an individual design package) and all changes thereto with regard to its adequacy and compliance with established practices and specified requirements. DRB members act as a body rather than individually.

Design, Final - Approved design output documents and approved changes thereto (NQA-1).

Deviation - A departure from specified requirements (NQA-1).

Director - For the purposes of this guidebook, the term "Director" shall include the Office of the Director and the Deputy Director.

Document - Any written, recorded, or pictorial information (e.g., instructions, procedures, drawings, and reports) that describes, defines, specifies, reports, or certifies activities, data, requirements, procedures, or results.

Document Control - The process of generating or revising a document; the management of documents, including identification, acquisition, processing, storage, and dissemination. The system will designate the process by which specified documents are reviewed for adequacy, approved for release, released and controlled by authorized personnel, and distributed to specified individuals, organizations, and locations.

Documentation - A collection of documents on a given subject; any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.

Dual Storage Facilities - Two record-storage facilities sufficiently remote from each other to eliminate the possibility of exposure to a simultaneous hazard.

Energy Conservation Report (ECR) - The report addresses DOE concerns that energy conservation is a project consideration. The report includes information on alternatives considered and an analysis of each. An ECR may be required by DOE on any project.

Engineering Analysis. A series of operations to produce information; typically involving the mathematical modeling of physical systems and processes, the performance of calculations to produce data for parameters that characterize the response of a system or the functioning of a physical process, the assembly of data in forms that facilitate interpretation to gain an understanding of phenomena of interest, and the determination, using knowledge of the physical sciences, of answers to specific questions concerning the response of a system or the results of processes. (NPR)

Environmental Assessment - A concise public document prepared by the user and ESH-8. This document helps determine whether preparation of an Environmental Impact Statement (EIS) is necessary; provides a way for an agency to show compliance with the National Environmental Policy Act (NEPA); and facilitates the preparation of an EIS when one is necessary.

Environmental Impact Statement - A formal public document that explains in detail the environmental impact of a proposed action. An EIS is prepared for a project only when required. Most Laboratory projects do not require an EIS.

Feasibility Study - A preliminary, informal investigation into a client's proposal or requirement that is necessary to meet client and Laboratory goals. Feasibility studies are initiated to provide conceptual information to the requester's management that will aid in the decision making process. The information provided is assembled from informed sources and indicates a generalized scope for the project, the feasibility of the proposal, a probable cost, the required funding type, and a recommended method of accomplishment. The cost at this point is only probable and not definitive.

Final Safety Analysis Report (FSAR) - See Safety Analysis Report.

Finding - A lack of compliance with any element of the LANL QA Program, applicable laws, or DOE orders that require certain corrective actions.

Finding. The characteristic or status of an activity that indicates that it may be a concern or a deficiency.

Government-Furnished Property (GFP) - Government-owned property provided to the construction contractor for inclusion in construction. GFP may include special tools, fixtures, hardware, material, and equipment, usually provided through the Laboratory.

Graded Approach - As used herein, a systematic approach that varies the application of the QA program to an activity or item based upon a review of the risk associated with the possible failure of that particular activity or item. Risk is more effectively managed by using a graded approach, applying lesser controls and formality to an activity having little or no risk than to an activity posing great risk.

Guideline - A suggested practice that is not mandatory in programs intended to comply with a standard. The word "should" denotes a guideline; the word "shall" denotes a requirement (NQA-1).

Hold Point - A mandatory inspection activity beyond which work shall not proceed until (1) an inspection is performed by a certified inspector and acceptance is authenticated; or (2) written release is authorized by the organization that established the hold point. All releases of specified hold points shall be documented in

accordance with established procedures before work continues and shall be included or referenced in the document requiring the hold point.

Important to Safety. Important to safety means those structures, systems and components that serve to provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public. It encompasses the broad class of plant features, covered (not necessarily explicitly) in the NPR General Safety Requirements (GSRs), that contribute in an important way to safe operation and protection of the public in all phases and aspects of facility operations (that is, normal operation as well as accident mitigation). (NPR)

Inspection - An examination or measurement by an inspector to verify whether an item or activity conforms to specified requirements (NQA-1).

Inspector - A person qualified by the Laboratory Quality Policy Office (LQPO) who performs inspection activities to verify conformance to specific requirements (Quality Operations Office Blue book, archaic).

Internal Audit. An audit of those portions of the NPR/SPO QA program retained under its direct control and within the NPR/SPO organizational structure. (NPR)

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

Lead Auditor - An individual trained, qualified, and certified to organize and direct an audit; report findings and concerns; and evaluate corrective action.

Lifetime Record - See Permanent Record.

Lifetime Records. Lifetime records include all safety records and quality assurance documents that would be of significant value in demonstrating the capability for safe operation of the NPR reactors and support facilities. (NPR)

Limited Calibration - A situation in which an instrument that has been calibrated does not meet all applicable specifications (after adjustments, if any); or an instrument calibrated over a limited subset of its available functions, ranges, or attributes.

Measuring and Test Equipment (M&TE) - Devices or systems used to calibrate, measure, gage, test, or inspect in order to control, or to acquire data for verifying, conformance to specified requirements (NQA-1).

Microform - Any hard copy miniaturized for handling and storage. Forms include microfilm, computer output microfilm, aperture cards, and optical disk data and output.

Minor Changes - Inconsequential editorial corrections that do not add, delete, or modify specified requirements.

Nonpermanent Record - Records required to show evidence that an activity was performed in accordance with specified requirements, but that need not be retained for the life of the item.

Nonconformance - Any deficiency in a physical characteristic, documentation, or procedure that renders the quality of an item or service unacceptable or indeterminate (NQA-1).

Nonconformance Report (NCR) - A written report describing a specific deficiency, the related technical or procedural requirements, and the initiating individual. The NCR also documents the agreed upon action and closure of the issue.

Objective Evidence - Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity that is based on observations, measurements, or tests that can be verified (NQA-1).

Observation - A program weakness that is not necessarily related to specific requirements, but that could lead to a more serious deficiency if not corrected. An observation does not necessarily constitute a lack of compliance (i.e., a finding) with applicable quality requirements. Observations may also include noteworthy practices.

Observer - An individual who is not an active participant in the audit process. The observer may be involved to learn how an audit is conducted or to become familiar with the audited organization and activities.

On-the-Job Training (OJT) - A method of planned, hands-on training (normally conducted in the work place) by which the student acquires experience and develops skills through actual task performance under the guidance and direction of a qualified worker, mentor, or instructor.

Owner - The person, group company, agency, or corporation who has or will have title to the nuclear power plant (NQA-1).

Peer Review - A documented, critical review performed by personnel independent of those who performed the work, but who have technical expertise at least equivalent to that needed to perform the original work. Peer reviews are in-depth, critical reviews and evaluations of documents, material, or data that require interpretation or judgment to verify or validate assumptions, plans, results, or conclusions, or material or data contained in a report.

Performance-Based Training - A systematic approach to training based on job tasks and the related knowledge and skills required for competent job performance.

Permanent Record - Records required to resume operations in the event of a disaster or to meet Federal, State, and DOE requirements. A "Lifetime Record" must be maintained by or for LANL for the life of the particular item, process, system, or activity being documented.

Personnel Qualification - The process of ensuring that certain specified characteristics and abilities, as measured against established requirements such as standards or tests, are possessed in sufficient degree by an individual to qualify him or her to perform a job adequately.

Pre-Title I - All those design activities, including conceptual design and design criteria, that are accomplished before Title I begins.

Preliminary Design (Title I) - Continuation of the design effort utilizing conceptual design and project design criteria as a basis for project development. Title I design develops data and determines the requirements and criteria that will govern the definitive design. Tasks include preparation of preliminary planning and engineering studies, preliminary drawings, and outline specifications.

Preliminary Safety Analysis Report (PSAR) - See Safety Analysis Report.

Primary Storage Facility - See Single Storage Facility.

Procedure - A document that specifies or describes how an activity is to be performed (NQA-1).

Process - A series of controlled administrative or physical actions that are designed to achieve a specific end or result.

Process Hazard - A hazard associated with the facilities and/or the functions essential to, or associated with, the production of a product, by-product, or waste. Process hazards are not associated with the construction of a facility or the development of a process, but only with the start-up, operation, and shutdown of a facility or process. Process hazards are also items or facilities that have been assessed as having the potential to result in an incident whose consequences will exceed any process hazard criterion.

Process Improvement - The act of reviewing, assessing, measuring, or identifying by other means particular steps or actions within an overall process that would benefit from change, and then taking specific action to implement the change. Quality improvement relies on process improvement, which can be attained by reducing duplicative or unnecessary actions and the variability associated with each process that influences the quality of the final work or product.

Procurement Documents - Documents generated in the act of purchasing an item or service, e.g., purchase requests, purchase orders, and checklists generated as part of the overall procurement activity and used to define and document the requirements of a procurement.

Procurement Quality Records - Completed procurement documents related to PR's, PO's, (e.g., QA Checklists, inspection reports, receiving reports, etc.) that furnish evidence of the quality of items and services required and rendered.

Program - An organized set of activities directed toward a common purpose or goal and undertaken or proposed in support of an assigned mission; characterized by a strategy for accomplishing one or more objectives and identifying the means of accomplishment, particularly in quantitative terms, with respect to manpower, material, and facility requirements. LANL programs typically include research and development (R&D) projects and supporting operations.

Project - A unique effort within a program that has firmly scheduled beginning, intermediate, and ending date milestones; prescribed performance requirements; prescribed costs; and close management, planning, and control.

Project Sponsor - The LANL organization requesting or sponsoring an activity or project. The internal customer is normally a research, operations, or engineering function having responsibility for the use, operation, or performance of the project item, facility, or process.

Purchase Order (PO) - Any subcontract for supplies (items) or services that is initiated by a LANL purchase request.

Purchase Request (PR) - Procurement document used to initiate a purchase order or subcontract.

Qualification Needs - The characteristics and abilities that an employee lacks when compared with a specific job's qualification standard. The employee's qualification needs must be met, normally through education, training, and experience, before he or she can be assigned or considered qualified to perform that job.

Qualification Standards - The characteristics or abilities normally gained through education, training, and experience that are needed to perform a specific job adequately.

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 (NQA-1).

Qualified Procedure - An approved procedure that has been demonstrated to meet the specified requirements for its intended purpose. Qualified Suppliers List (QSL) - A listing of offferors that have been qualified from a QA perspective to provide critical items and services.

Qualified procedure - An approved procedure that has been demonstrated to meet the specified requirements for its intended purpose (NQA-1).

Quality - The degree to which an activity, item, or process meets or exceeds the customer's or end user's specified requirements.

Quality Assurance (QA) - A process of using management tools, e.g. procedures, systematically developed and implemented by an organization, including both management and staff, that aid the organization in producing and continually improving its products, and gives confidence that those products at least meet customer operational, functional and technical requirements and expectations.

Quality Assurance Record - A completed document that furnishes evidence of the quality of items or activities that affect quality (NQA-1).

Quality Categories. Application of quality assurance criteria is dependent on the importance of the item to the safety and mission of the NPR Program. The Los Alamos NPR/SPO responsibilities are to support DOE-NP/OSQ in *assuring* that safety is achieved; the NPR engineering organizations and their contractors have the responsibility for *achieving* safety through design, construction, and operation. Therefore, the application of quality categories to Los Alamos NPR/SPO activities will be a graded approach based on the importance of the activity in supporting safety-related "regulatory" decisions by DOE. These decisions, and their supporting documentation, comprise the NPR safety record. The quality categories, as derived from the NPR Quality Assurance Requirements Document (QAR), shall be used (see below). (NPR, archaic)

Quality Category G (QC-G). This quality category includes support and other systems, which, for the purpose of the NPR Quality Assurance Program, are defined as those facilities, structures, systems, and components that fall within the program boundary but are not covered in the categories defined above. Los Alamos NPR/SPO activities, including exploratory analysis and studies, that do not support the formal safety record fall in this category. These activities shall be conducted according to NPR/SPO office procedures and/or the Los Alamos National Laboratory Manual, and in accord with good engineering practices. (NPR, archaic)

Quality Category M (QC-M). This quality category includes structures, systems, and components, that are mission or production related. Los Alamos NPR/SPO will review mission-related structures, systems, and components that are important to safety following the process outlined above for Quality Category "S" activities. (NPR, archaic)

Quality Category S (QC-S). This category includes structures, systems, and components that are *important to safety*. Los Alamos NPR/SPO activities that directly support the formal NPR safety record fall in this category. (NPR, archaic)

Quality Control - is the process through which the actual quality performance of a product is measured, compared with an applicable standard or specifications, adjusted to at least meet the standard. Steps in the process are:

- 1. Choosing the control subject.
- 2. Choosing a unit of measure.
- 3. Setting a standard or goal for the control subject.
- 4. Choosing a sensing device which can accurately measure the control., subject in term of the unit of measure.
- 5. Measure the performance.
- 6. Interpret the difference between actual measurement and the standard. Adjust the process to eliminate the difference.

Quality Improvement - A dual fold process of addressing and remedying sporadic problems, sudden adverse changes in the status quo of a work process, and solving chronic problems, long-standing adverse conditions in a work process, i.e. continual scrap of several percent, to improve a work process by changing the status quo to a new improved level. (Derived from ***Quality Planning and Analysis,*** by J. M. Juran and Frank M. Gryna, Jr., McGraw-Hill, 1980, p. 99.)

Quality Level (archaic)- A means of defining the extent to which QA controls will be applied to items or activities. The quality grading system is based on such criteria as;

- (1) consequence of failure,
- (2) probability of failure,
- (3) data generation function,
- (4) complexity of design or fabrication uniqueness,
- (5) special controls, (6) ability to demonstrate functional compliance,
- (7) quality history, (8) degree of standardization, and
- (9) impact on schedule or cost, or both.
- **<u>Note</u>: This is superseded by method of graded approach.**

Quality Plan (QP) - A document generated at the inception of a program or project describing the program, its designated Quality Category, applicable requirements, and any customer-imposed QA requirements. A QP lists the organizations involved in implementing the quality-affecting activities.

Quality-Affecting Activities - Those activities associated with the attainment and verification of quality objectives, accomplishing work in a quality manner, and assuring the adequacy of the implementation of the quality program set forth herein.

Readiness Review - A structured method for determining that an activity is ready to operate or to proceed to the next phase. As a minimum, it includes a comprehensive review of the readiness of the hardware, personnel, and procedures associated with a project or program milestone. The review also includes a determination of compliance with all requirements.

Receipt Inspection - QA activities performed by a qualified individual to verify the attributes of an item.

Receiving - Taking delivery of an item at a designated location (NQA-1).

Record - A complete document or other media that provides objective evidence of the quality of an item or process.

Records Source - The LANL organization(s) that generates documents that become QA records.

Reject - A disposition that identifies nonconforming items as unacceptable for quality assurance use. A rejected item shall be physically segregated from acceptable items and scrapped or returned to the supplier, as appropriate.

Repair - The act of restoring a nonconforming characteristic to an operating condition so that the capability of an item to function reliably and safely is unimpaired, even though that item still may not conform to the original requirement (NQA-1).

Repository - A center for the accumulation or storage of QA records.

Requester - The requesting individual or organization initiating a procurement.

Retention Period - The length of time a record must be kept.

Retrieval - The act or process of retrieving, getting back, or recovering a record from its temporary file or permanent storage location.

Rework - The actions that make a nonconforming item conform to original drawings or specifications through completion, re-machining, re-assembly, or other corrective means (NQA-1).

Risk - The quantitative or qualitative expression of possible loss that considers both the probability of event occurrence causing harm or loss and the consequences of that event.

Safety Analysis Report (SAR) - A safety document that provides a complete but concise description and safety evaluation of the site, design, normal and emergency operations, potential accidents and their predicted consequences, and the means proposed to prevent such accidents and/or reduce their consequences to acceptable levels. An SAR is designated as final (FSAR) when it is based on final design information; otherwise, it is designated as preliminary (PSAR).

Safety Assessment - A Laboratory document prepared when (1) the DOE Environmental Checklist for a new or greatly modified facility or operation provides insufficient information to determine the need for a detailed safety analysis, or (2) the risks of an existing operation are not documented sufficiently to determine whether a detailed safety analysis is needed.

Safety Review. A safety review is a formal evaluation of the safety submittals from the NPR Engineering Technology Office (ETO) and its design/construction/operating organization(s). Its purpose is to provide independent assurance that NPR programmatic safety objectives (management, quality assurance, and technical safety requirements) in design, construction, testing, and operation phases are achieved, and that the health and safety of the public, operations personnel, and environment are adequately protected. Formal safety submittals include the Integrated Safety Analysis Report (ISAR), segments and amendments thereof, topical safety issue reports, and all directly supporting safety documentation (NPR, archaic).

Secondary Storage Facility - See Dual Storage Facilities.

Self-Assessment - A comprehensive management evaluation of individual Laboratory organizations to determine their achievement of organizational objectives associated with quality, quality assurance, and related safety and environmental requirements.

Self-Verification - An examination or measurement to determine conformance to specifications conducted under the direction of the organization that produced the items or activity to be verified. Self-verification shall be done by qualified individuals who may or may not be from the organization that originally performed the work or activity.

Senior Management - That level of Laboratory line management that includes Division Leaders and above, including the Director.

Sensitive Documents. Sensitive documents include all those NPR documents that contain proprietary information and/or competition-sensitive information, Applied Technology (AT) reports, and Unclassified Controlled Nuclear Information (UCNI) reports.

Service - The performance of work such as design, fabrication, inspection, nondestructive examination, repair, or installation (NQA-1).

Shall - (see definition of the term guideline).

Should - (see definition of the term guideline).

Single Storage Facility - One central, record-storage facility with little or no record duplication. The design and construction of single record-storage facilities shall meet the criteria specified herein.

Software Design Description (SDD) - A representation of a software system created to facilitate analysis, planning, implementation, and decision making; a blueprint or model of the software system. The SDD is used as the primary medium for communicating software design information.

Software Life Cycle - The period of time that starts when a software product is conceived and ends when the product is no longer available for use..

Software Quality Assurance Plan - A document that identifies the particular quality assurance procedures and documentation associated with the development, modification, and maintenance of computer software.

Software Quality Assurance Plan. A plan for the development of software products necessary to provide adequate confidence that the software conforms to established requirements. (NPR)

Software Requirements Specification - Documentation of the essential requirements (functions, performance, design constraints, and desired attributes) of the software and its external interfaces.

Software Validation. The test and evaluation of the completed software to ensure operations specified in numerical models are correctly performed and comply with software requirements.

Software Verification. The process of determining whether or not a computational method is a correct representation of the process or system for which it is intended and meets software requirements of the previous phase.

Source Evaluation Board - A procurement evaluation group consisting of LANL personnel, including MAT representatives, that determines the relative capabilities of offerors on procurements.

Special Process - A process in which results are highly dependent on the control of the process or the skill of the operator, or both, and for which the specified quality cannot be readily determined by inspection or test of the product. Special processes addressed in this guidebook include the nondestructive examination processes of radiography, ultrasonic, and dye-penetrant examination; magnetic-particle and eddy-current testing; leak testing; the destructive processes of metallography and shock testing; and the fabrication processes of welding, brazing, soldering, coating, adhesive bonding, and heat treating .

Specification - A detailed, descriptive statement of the technical and physical features of an item or service, including statements of work, tests to be performed, special operating conditions, deliverables, and accept/reject criteria.

Standard Terms. The Definitions of Standard terms may be found in the NPR/SPO Quality Assurance Program Description, LA-NPR-2, Rev. 2, May 1, 1991. Terms include: Important to Safety, Lifetime Records, Nonpermanent Records, Safety Documents, Safety Records, and Sensitive Documents. (NPR)

Standards - When used in software QA, those mandatory conventions and practices employed and enforced that prescribe a uniform, disciplined approach to software development and maintenance.

Standards Laboratory - One of the service organizations designated by LANL to perform calibrations for employees throughout the Laboratory. There are two such organizations: the ESH-9 Standards and Calibration Laboratory and the ESH-4 Health Physics Measurements' Instruments/ Calibration Section.

Status Indicator - Written, pictorial, or other visual or recorded information describing the status of an item.

Subject Matter Expert (SME) - An individual who has professional expertise on a particular topic.

Supplier - Any individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their subtier levels (NQA-1).

Support Services Subcontractor (SSS) - The organization that performs, under subcontract to the Laboratory, a number of services in support of Laboratory activities. Such services include plant maintenance, custodial, provision of utilities, and minor construction.

Surveillance Inspection - The witnessing of the important elements of a process or activity over a sufficient period of time to make an informed judgment as to its acceptability. Surveillance inspections are performed by a

certified inspector in accordance with approved procedures or checklists, which provide documentation of the result.

Surveillance. The act of formally monitoring or observing to verify whether an activity conforms to specified quality requirements. (NPR)

System Description - A summary document that describes specific functions, design bases, and major features of a system or subsystem and aids in understanding the basic design approach.

Systems Software. Software designed for a specific computer system or family of computer systems to facilitate the operation and maintenance of the computer system and associated programs, for example, operation systems, compilers, and utilities. (NPR)

Task Leader - The person responsible for managing the project and ensuring that all quality assurance procedures are met. The task leader will usually delegate responsibility for certain quality assurance tasks.

Technical Authority - The LANL scientists, designers, lead engineers, or others in technical roles who have primary technical accountability for an aspect of a program under the Technical Management Authority.

Technical Management Authority - Program managers, project or line managers, principal investigators, project engineers, and others similarly designated who have direct management responsibility for directing and overseeing a task or project.

Technical Review - A documented, traceable review performed by qualified personnel independent of those who performed the work, but who have technical expertise at least equivalent to that needed to perform the original work. Technical reviews are in-depth, critical reviews, analyses, and evaluations of documents, material, or data that require technical verification and/or validation for applicability, correctness, adequacy, and completeness. The documents, material, or data being reviewed are within the existing state of current technology.

Technical Specialist - An active participant in the audit process, including assistance in preparation and concurrence of audit checklists and the verification of technical attributes of specialized activities to audit program implementation and effectiveness; an Audit Team Member. The technical specialist will have basic training in the audit process, auditor skills, and indoctrination on the applicable requirements of DOE Order 5700.6B, DOE Order 5700.6C, 10 CFR 50 Appendix B, and ASME NQA-1, as applicable.

Test Case. A specific set of test data and associated procedures developed for a particular objective, such as to exercise a particular program path or to verify compliance with a specific requirement (NPR)

Test Plan. A document describing the approach to be taken for intended testing activities. The plan typically identifies the items to be tested, the testing to be performed, test sequences, personnel requirements, and evaluation criteria. (NPR)

Testing - The determination of the capability of an item or process to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

Testing. The process of exercising or evaluating software and/or a computer system to verify that it satisfies specified requirements or to identify differences between expected and actual results. (NPR)

This definition includes not only those structures, systems, and components that perform safety functions and traditionally have been classified as safety-related or safety-grade, but also those that place frequent demands on or adversely affect the performance of safety functions if they fail or malfunction. Thus these latter structures, systems, and components would be subject to applicable GSRs to a degree

commensurate with their contribution to risk. In applying this definition, it is recognized that during the early stages of the design effort, all significant systems interactions may not be identified and only the traditional interpretation (safety-related) may be practical. However, as the design matures and results from probabilistic risk assessments identify vulnerabilities resulting from non-safety-related equipment, additional structures, systems, and components may be included within this definition. (NPR)

Title I - See Preliminary Design, Title II - See Definitive Design.

Traceability - The ability to relate individual measurement results through an unbroken series of calibrations to one or more of the following:

- (1)U. S. national standards maintained by the National institute of Standards and Technology;
- (2) national standards of other countries which are correlated with U. S. national standards;
- (3) accepted values of fundamental physical constants ;
- (4) values derived by the ratio type of self calibration techniques;
- (5) values obtained using nationally accepted measurement systems; or
- (6) comparison with consensus standards.

Training - Any activity conducted for the purpose of imparting knowledge or skill, teaching by example and experience, or making proficient with specialized instruction and practice. Included in this term are activities that teach, instruct, educate, tutor, train, discipline, or drill. In this guidebook, the word "training" is used rather than "education" to emphasize the preparation of employees to do their jobs well.

Training Program - A planned, organized sequence of activities. A training program prepares individuals to perform their jobs, to meet specific position or job-classification qualification needs, or to maintain or improve their job performance.

Training. Instruction given, as necessary, to Los Alamos personnel engaged in NPR safety reviews and quality-affecting activities that the NPR/SPO Director, or his/her designee, deems necessary to maintain or develop qualifications, improve quality of work, or meet DOE/NP-specified requirements. (NPR)

Trend Analysis - Those actions that identify repetitive, recurring conditions that produce unacceptable items or services. Trend analysis also provides evidence when changes to an item, analysis, support activity, product, system process, structure, activity, etc. are occurring in time. A trend-analysis study may be used as justification for authorizing change.

Uncertainty - An estimate of the range of values about the measured value in which the true value is believed to lie.

Uncontrolled Information - Documents not having receipt requested distribution, unique identification, revision status, or physical control limited to authorized individuals.

Use-As-Is - A disposition that may be imposed for a nonconformance when it can be established that a discrepancy will result in no adverse conditions and that the item or service is satisfactory for its intended use (NQA-1).

User - Individual or organization deriving primary benefit from a program, project, item, or activity.

User Documentation - Documentation describing the way a system or component is to be used to obtain desired results.

Validation and Verification of Software - (See Software Validation and Software Verification)

Verification - The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements (NQA-1).

Verification and Validation (V&V) - In software QA, the process of determining whether the requirements for a system or component are complete and correct, whether or not the products of each development phase fulfill the requirements or conditions imposed by the previous phase, and the final system or component compliance with specified requirements.

Version Index. An index to versions of the original facility input deck (base deck) that is kept at the beginning of the base Input Deck Design File. (NPR)

Waiver - Documented authorization to depart from specified requirements (NQA-1).

Witness Point - A verification activity that requires the assigned inspector to be notified in advance for the purpose of verifying activities such as observing a specific step in a procedure or verifying current calibration of equipment. A witness point differs from a hold point in that work may proceed without verification being completed if permitted by the assigned inspector.

Work - The process of performing a defined task or activity, e.g., research and development, operations, administration, inspection, construction, manufacturing, or fabrication.

Work Process - A planned mix of people, equipment, environmental conditions, supply, management support, resources, and requirements to achieve an objective. It includes all activities involved in performing the defined tasks or objectives; such activities as planning, scheduling, accounting, project management, design, analysis, fabrication, procurement, construction, installation, testing, operation, modification, maintenance, and decommissioning.

Working Copy - An uncontrolled copy of a controlled quality-related document. A working copy is produced for use by an individual who is not designated for receipt of the document by either controlled distribution or controlled identification listings.