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INTRODUCTION

The NSNFP Documents Manual contains the Quality Assurance Program Plan, the Quality Assurance Requirements Document (QARD) Requirements Matrix, and the implementing procedures applicable to the National Spent Nuclear Fuel Program (NSNFP). These documents implement the QARD, DOE/RW-0333P, as it applies to the line management activities and QA organization activities of the NSNFP.

The content of the NSNFP Documents Manual can be accessed from the NSNFP Homepage. NSNFP forms are accessed exclusively from the NSNFP Homepage.

The shaded areas of Figure 1 represent the general content of the manual. Together the Quality Assurance Program Plan and the QARD Requirements Matrix form a summary of the program implemented by the NSNFP. The implementing procedures referenced by the matrix are identified as Program Management Procedures (PMPs), Program Support Organization (PSO) procedures, and Quality Assurance Staff (QAS) procedures. The procedure numbering system aligns with the most predominant QARD section addressed by the procedure.

Program Management Procedures

> Program Management Procedures prescribe administrative processes applicable to the activities performed by or affecting all NSNFP personnel.

Program Support Organization Procedures

> PSO procedures are applicable to the activities delegated to the PSO for execution.

Quality Assurance Staff Procedures

> QAS procedures are applicable to the activities delegated principally to the QAS assessment function and extend to the corrective action, trending, and tracking processes that serve the NSNFP.

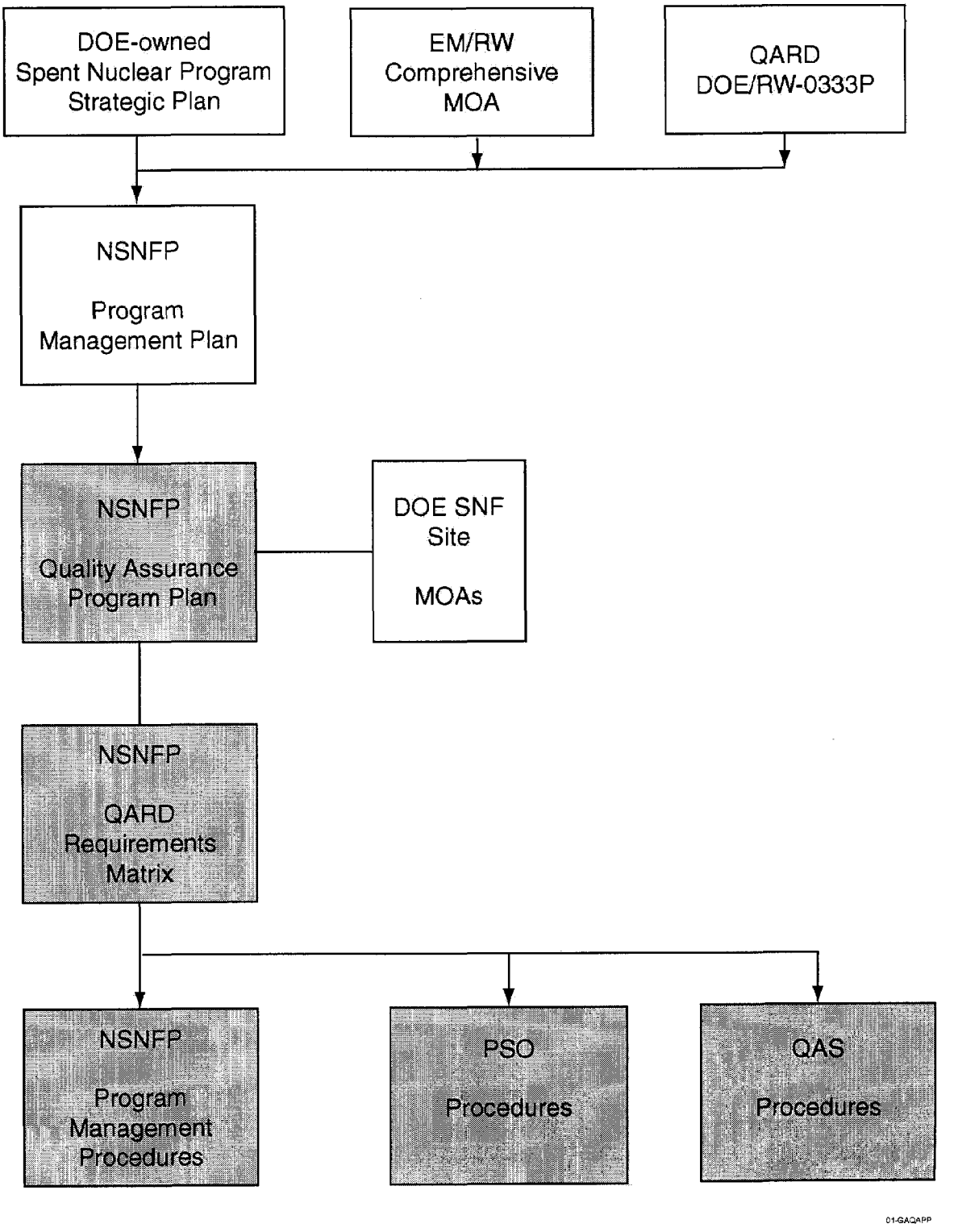

Figure 1. NSNFP Documents Manual general content (in shaded areas).

GLOSSARY

The NSNFP Glossary is composed of QARD glossary terms and other terms used by NSNFP in QA Program implementing documents. These terms may appear in *italics* within implementing procedures and implementing documents followed by (see glossary).

Acceptance (document). The documented determination by the receiving organization that work is suitable for the intended purpose.

Acceptance Spent Fuel Database. The working database used by PSO Technical staff to update information. It allows access to all edit functions of individual records within the database,

Action to Prevent Recurrence. The actions taken to correct a specifically identified root cause of a significant adverse condition.

Activity. A distinct work effort segmented into actions associated with a performing organization. Also referred to as a task or subtask.

Activities affecting quality. Deeds, actions, processes, tasks, or work that influence the achievement or verification of program quality requirements and objectives.

Acquisition. A product or service obtained by or on behalf of the NSNFP for the program's possession, use, or consignment of use to others.

Adverse Quality Trend. An elevated frequency of a deficiency occurring within a calendar year; or an increase in frequency over time of the occurrence of a deficiency. The deficiencies shall meet one of the following criteria:

- Deficiencies indicate multiple occurrences of the same deficiency within one process or group of similar processes
- Occurrence of similar deficiencies by one or more individuals within one process.

Alternate Calculations. Calculations that are made with alternate methods to verify correctness of the original calculation.

Application (Software). (1) Software designed to fulfill the specific needs of a user. (2) Software that is written where the user prescribes one or more instructions to generate data, manipulate data, or perform calculations.

Approval. The documented determination by a responsible organization that work is suitable for the intended purpose and shall be used as required.

Assessment. An evaluation of a program or activity performed either by an audit, surveillance, or management assessment.

Audit. A planned and documented quality assurance program verification performed to determine by investigation of objective evidence the adequacy of and compliance with established implementing documents and the effectiveness of implementation.

Audit Team Leader. A lead auditor who is assigned to direct the efforts of an audit team.

Auditor. An individual who is qualified to perform assigned portions of an audit.

Baseline Element (Software). An individual software component (e.g., requirements document, design document, or source code) that is under configuration management control.

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

Certification. The act of determining, verifying, and attesting in writing to the achievement or compliance with specified requirements.

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

Characterization. Performance activities such as data collection, testing, inspections, document preparation, or analyses necessary to describe DOE SNF for acceptance, storage, transportation, and disposal (this includes preclosure and postclosure performance in the repository).

Clean Platform. A computer that has never had the SFD loaded on it or has been configured to have software identical to a new computer from the factory.

Compliance-based Audit. A planned and documented activity performed to determine by investigation, observation, 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.

Computer Program. A sequence of instructions suitable for processing by a computer.

Concern. Condition observed during a QA audit or surveillance that is not a condition adverse to quality but deserves management attention.

Condition Adverse to Quality. A state of noncompliance with quality assurance requirements or implementing document; a failure, nonconformance, malfunction, deficiency, deviation or defect in material, components, or systems important to safety.

Conditioning. Any process that prepares or treats DOE SNF for storage, transportation, or disposal in accordance with regulatory requirements.

Confirmatory Testing. An evaluation subject to implementing documents that investigates the properties of interest of data in an attempt to confirm the quality of the data.

Controlled Document. A document that is prepared, reviewed, and approved in accordance with established implementing documents; subject to controlled distribution; and subject to a defined change process.

Corrected During Audit (CDA). A condition adverse to quality that is determined by the certified auditor or lead auditor to be an isolated condition and that is corrected by the responsible organization during an audit or surveillance. A corrective action is verified as complete by the auditor or lead auditor before concluding fieldwork. All CDAs will be documented in the CATTS database to allow trending.

Corrective Action. Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

Corrective Action Coordinator (CAC). An individual within NSNFP QAS designated to receive, coordinate, and track documentation that supports corrective action activities.

Corrective Action Tracking Trending System (CATTS). Database used to track conditions adverse to quality and support trend analysis.

Data (collected). Factual information obtained from investigation activities such as sample collection, physical measurements, testing, and analyses, both in the field and the laboratory.

Data Reduction. Processes that change the form of expression, quantity of data or values, or the number of data items.

Database. A collection of previously distinct data (not created by the database) that have been logically organized to facilitate data access.

Deficiency Report (DR)/Corrective Action Request (CAR). A form used to document conditions adverse to quality and significant conditions adverse to quality. The form provides a record of the identification and evaluation of remedial actions and actions to prevent recurrence, and verification of completion of corrective actions.

Design Bases. Information that identifies the specific functions to be performed by items and the specific values or ranges of values chosen for controlling parameters as reference bounds for design.

Design Change. Any revision or alteration of the technical requirements defined by approved and issued design output documents, and approved and issued changes thereto.

Design Input. Those criteria, parameters, bases, or other design requirements upon which design output documents are based.

Design Output. Drawings, specifications, and other documents resulting from the translation of design input requirements of items.

Design Process. Technical and management process that commences with identification of design input and ends with the issuance of design output documents.

Design Review. A documented evaluation of design output during the design process to determine design adequacy and conformance to specified acceptance criteria.

Direct Cause. The apparent cause of a condition adverse to quality.

Direct Cause Code. The direct cause code reflects the apparent and predominant cause of a condition adverse to quality.

DOE SNF Sites. The Spent Nuclear Fuel Program DOE entities and their Management and Operations (M&O) or Management and Integration (M&I) contractor entities associated with the DOE Savannah River Operations Office, the DOE Oak Ridge Operations Office, the DOE Idaho Operations Office, and the DOE Richland Operations Office.

Document Control. The process for controlling documents that provides for adequacy review, approval for release by authorized personnel, and distribution for use at the prescribed work locations.

Document Statusing. The annotation on a document that includes the terms: Draft or Draft A, B, C, etc.; Preliminary; or Predecisional. The term Draft or Draft A, B, C, etc., may be used apart or in combination with the terms Preliminary or Predecisional. The term "Approved" may be used directly or implied as evidenced by approval signatures with the absence of the preceding terms above or with the inclusion of the term Final. Other document statusing terms may be defined in the document itself.

Editorial Corrections. Editorial corrections are limited to those changes that correct grammar, spelling, section renumbering that does not alter the sequence of work, document titles, document numbers, or organizational titles that do not change roles and responsibilities within NSNFP interfacing organizations.

End Users. NSNFP personnel, by individual or functional position, who are responsible for accomplishing action steps within NSNFP implementing procedures or documents.

External Documents. Documents generated and approved by an entity other than the NSNFP. External documents include those documents submitted by NSNFP suppliers and those provided by Office of Civilian Radioactive Waste Management (OCRWM or RW) to NSNFP.

Government Sector Supplier. A government agency that provides products or services to the NSNFP. Government Sector Suppliers typically reside within the DOE complex and include M&O and M&I contractors performing work for the DOE SNF Program. Government Sector Suppliers may reside within another government agency.

Implementation (Software). The process of translating the software design into a computer program.

Indoctrination. Method of training designed to familiarize personnel in fundamental criteria, program elements, responsibilities, and authority applicable to assigned tasks.

Information-Only Copies. As status or marking given to copies of controlled documents that are sent to individuals or functional positions that have no action steps to be performed in the document and are not required to be trained in the document.

In-process lead auditor qualification records. For individuals permanently assigned to the NSNSP that perform lead auditor functions, the lead auditor qualification records are retained as in-process records until the individual terminates from the NSNFP. Training and qualification records for lead auditors, auditors, and technical specialists assigned to perform a single audit or surveillance are captured and processed as part of the audit or surveillance record.

In-process training records. Training records stipulated by NSNFP procedures are held as in-process until the employee terminates from the NSNFP.

Inspection. A quality assurance program verification that is used to verify whether an item conforms to specified technical criteria.

Interagency Agreement. A financial and working interface with another federal agency prior to initiating procurement requests with the agency.

Internal Documents. Documents generated by the NSNFP in accordance with NSNFP procedures.

Interoffice Work Order (IWO). (Also known as an Interdepartmental Work Order [IDWO])—DOE's method for transferring funds and associating the funds with a scope of work. The IWO system is used when one DOE contractor performs work for another contractor or field office. Other methods for transferring funds are available.

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

Lead Auditor. An individual who is certified to organize, perform, and direct an audit; report audit results; and evaluate related corrective actions.

Macro. Single computer instructions invoked by a symbol, name, or key that represents commands, actions, or keystrokes.

Management Assessment. A quality assurance program verification that is conducted by management above or outside the Quality Assurance organization and that evaluates the scope, status, adequacy, programmatic compliance, and implementation effectiveness of the quality assurance program.

Measuring and Test Equipment. Devices or systems used to calibrate, measure, gauge, test, or inspect in order to control or acquire data to verify conformance to specified requirements.

Model. A representation of a process, system, or phenomenon, along with any hypotheses required to describe the process or system, or explain the phenomenon, often mathematically.

Model, Abstraction. A product of the abstraction process that meets the definition of a mathematical model.

Model, Conceptual. A set of hypotheses consisting of assumptions, simplifications, and idealizations that describes the essential aspects of a system, process, or phenomenon.

Model, Mathematical. A mathematical representation of a conceptual model (system, process, or phenomenon) that is based on established scientific and engineering principles and from which the approximate behavior of a system, process, or phenomenon can be calculated within determinable limits of uncertainty.

Model, Process. A mathematical model that represent an event, phenomenon, process, component, etc., or series of events, phenomena, processes, or components, etc. A process model may undergo an abstraction for incorporation into a system model.

Model, System. A collection of interrelated mathematical models that represents the overall geologic repository or overall component subsystem of the geologic repository.

Model Validation. A process used to establish confidence that a mathematical model and its underlying conceptual model adequately represents with sufficient accuracy the phenomenon, process, or system in question.

NRC-licensed Activities. Those activities that directly support analyses covered under 10 CFR 63, 71, or 72.

NSNFP Direct Support Organizations. Consist of the NSNFP Program Support Organization (PSO) and the NSNFP Quality Assurance Staff (QAS) Organization.

Nonconformance. A deficiency in characteristics or record that renders the quality of an item or sample unacceptable or indeterminate.

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

Organizational Interface. The relationship between organizations when one organization prescribes an activity or requirement to, or shares an activity or requirement with, another organization.

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

Peer Review. A documented, in-depth critique of work by a group of peers independent from the work being reviewed.

Performance-based Audit. An audit methodology in which processes or activities are evaluated based on their expected results to allow subsequent conclusions to be drawn about the adequacy

of the products and the adequacy and effectiveness of the processes or activities associated with those products.

Process. A series of actions that achieves an end result or accomplishes work.

Procurement Document. Purchase orders, contracts, specifications, or other documents used to define technical and quality assurance requirements for the procurement of items or services.

Production Spent Fuel Database. The released version of the database used by various individuals to view information and storage details about specific spent nuclear fuels. This database, maintained by PSO, only allows users to view information, no editing of records is allowed. All user queries are made against the Production SFD.

Program Support Organization (PSO). *Consists of technical and support staff reporting to the PSO Manager.*

PSO Quality Engineer (QE). Individuals who are matrixed from QAS to PSO.

QAS Organization. Consists of QA auditors, lead QA auditors, and corrective action coordinators reporting to the QAS Manager.

QAS (Personnel). Serve as points of contact between the NSNFP and DOE SNF sites and interact with the NSNFP QAPM through the QAS Manager.

Quality Disputes. Differences of opinion involving the QA program that originate through normal work processes or emergent conditions.

Qualification (Personnel). The capabilities gained through education, training, or experience that qualify an individual to perform a required function.

Qualification of Data. A formal process that is intended to provide a desired level of confidence that data are suitable for its intended use.

Qualification Testing. A test that is intended to provide a desired level of confidence that an item meets specified criteria.

Quality Assurance. All those planned and systematic actions necessary to provide adequate confidence that an item will perform satisfactorily in service.

Quality Assurance Record. A completed document (or other medium) that furnishes evidence that items or work comply with requirements.

Quality-affecting Activity. Any aspect of NSNFP work that may affect the safety and protection of workers, the public, or the environment or the verification of the work.

Release (Software). The formal notification and distribution of approved software.

Relevant Experience. Relevant work experience is composed of performing similar functions with similar responsibilities within the nuclear industry to include work in commercial nuclear power generation, nuclear fuel production, nuclear fuel reprocessing, nuclear fuel storage, or transportation of nuclear fuel, or work at a DOE Laboratory. Where an academic degree is required or credited for work experience, the type of degree must support the individual's functional responsibility within the NSNFP.

Remedial Action. The actions taken to correct specifically identified conditions adverse to quality.

Requisition. A document within the INEEL M&O contractor's procurement system used to communicate work scope and requirements from a project or program to the procurement organization and ultimately to the prospective suppliers.

Responsible Organization (Corrective Action). The organization responsible to correct a condition adverse to quality.

Responsible PSO Technical Lead. As used in NSNFP procedures, an individual trained as an NSNFP PSO technical lead who is assigned to manage the day-to-day work associated with a control account depicted in the NSNFP Program Management Plan.

Right of Access. The procurement requirement that permits the purchaser or designated representative to enter the premises of a supplier for verification purposes.

Root Cause (Root Cause Code). The identified cause of a condition adverse to quality that, if corrected, will preclude recurrence or greatly reduce the probability of recurrence of the same or a similar condition adverse to quality.

Sample. A physical part of a whole whose properties are studied to gain information about the whole.

Scientific Investigation. Any observation, identification, description, experimental study, or analysis and explanation of natural phenomena.

Scientific Notebook. A record of the methodology and results of scientific investigations that is used when the work involves a high degree of professional judgment or trial and error methods or both.

Service. The performance of activities such as design, fabrication, inspection, nondestructive examination, repair, or installation.

Significant Condition Adverse to Quality. *NSNF Program—SNF sites*—A condition adverse to quality that, if uncorrected, could have a serious effect on safety or the ability to isolate waste. The following criteria are recommended to be used to determine if a condition is considered significant:

- A condition determined to be repetitive in nature that could impact SNF acceptance activities by DOE/RW

- A condition indicating a QA program breakdown
- A condition that, were it to remain uncorrected, could have an adverse impact on the ability to meet SNF acceptance criteria of DOE/RW-Waste Acceptance Systems Requirements Document (WASRD)
- A condition that could result in invalid or indeterminate SNF qualification data
- A condition that could result in invalid or indeterminate SNF records.

Site Characterization. The program of exploration and research both in the laboratory and the field that is undertaken to establish the geologic conditions and the ranges of parameters of a particular site that are relevant to the implementing documents.

Software. Computer programs, procedures, rules, and associated documentation pertaining to the operation of a computer system.

Software Baseline. A specification or product that has been formally reviewed and agreed upon, that thereafter is the basis for further development, and that can be changed only through formal change procedures.

Software Control Point. Milestones in the software life cycle when controls are applied to the software in which they are baselined prior to proceeding with the software project.

Software Item. Source code, object code, job control code, control data, or a collection of these items that function as a single unit.

Software Life Cycle. A series of activities that begins when the software product is conceived and ends when the software product is no longer available for routine use.

Software Routine. A collection of computer macros or script files, a spreadsheet application, or other stand-alone software application (either acquired or developed) that generally operates within another program, such as a spreadsheet, and must be independently verified by visual inspection and/or hand calculation.

Software Validation. The test and evaluation of completed software to ensure compliance with software requirements.

Software Verification. The process of determining whether the products of a given phase of the software development cycle fulfills the requirements imposed by the previous phase.

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.

Staff Augmentation. An individual trained in accordance with NSNFP implementing procedures who performs action steps within NSNFP implementing procedures but is not otherwise assigned

to NSNFP. Staff augmentation personnel do not appear on NSNFP organization charts. Staff augmentation sources include private sector suppliers or Government Sector Suppliers.

Stop Work. A formal directive issued by management that work must be stopped until resolution of the related significant condition adverse to quality.

Subject Code. The subject code reflects the predominant QARD requirement violated in a DR/CAR. Each subject code represents a QARD requirement.

Subject Matter Expert. An individual recognized by his or her peers as an authority on a specific topic.

Supplier. Any individual or organization that 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, or subcontractor.

Surveillance. The act of observing real-time activities and/or reviewing documentation to verify conformance with specified requirements and to evaluate their adequacy and effectiveness.

Technical Baseline Documents. Documents as defined in the Comprehensive Memorandum of Agreement (CMOA) between DOE Office of Environmental Management and OCRWM for Acceptance of Department of Energy Spent Nuclear Fuel and High-Level Radioactive Waste. Refer to Appendix C of the CMOA.

Technical Specialist. An individual who is assigned to an audit team when the scope, complexity, or special nature of the work to be audited warrants assistance from a technical standpoint.

Technical Work. The DOE SNF-related work of engineers, scientists, technicians, operators, QA professionals, and others that contributes to the content of designs, studies, tests, or scientific investigations or represents the execution of actions within NSNFP Program implementing procedures. Technical work does not include budget and schedule preparation, office support, stakeholder interaction, or other general administrative tasks.

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.

Testing. An element of verification for the determination of 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, data, or sample using recorded documentation.

Training. Systematic process provided to personnel so that they achieve proficiency, maintain proficiency, and adapt to changes in technology, methods, processes, or responsibilities as necessary to perform assigned tasks.

Transparent. A document is transparent if it is sufficiently detailed as to purpose, method, assumptions, inputs, conclusions, references, and units, such that a person technically qualified in the subject can understand the document and ensure its adequacy without recourse to the originator.

Trend Analysis. The periodic structured review process applied to deficiencies identified through assessments performed by the NSNFP; assessments of the NSNFP performed by external organizations; and inputs received from DOE SNF sites. This trending process includes tabulating deficiencies, assigning a cause code for each deficiency, correlating deficiencies by areas, identifying elevated frequencies of codes, identifying an increases in the frequency that a deficiency occurs over time, validation of the assigned codes, and determining adverse trends that require correction.

Use-As-Is. A disposition permitted for a nonconforming item 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 items, processes, services, or documents conform to specified requirements.

Work. Activities that are subject to the *Quality Assurance Requirements and Description.*