QUALITY OF SCIENTIFIC DATA: A REVIEW

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quality assurance note

Nuclear Waste Management Projects

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A Quality Assurance Note contains information thought to be of Laboratory wide interest. The subject matter always pertains to quality assurance.

The author of the Quality Assurance Note assumes full responsibility for its content.

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Approved for distribution

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Wayne Devlin is a colleague who works for the Westinghouse Hanford Company in Richland, WA. In 1984, he published a report entitled "Quality of Scientific and Engineering Data". 1) In the Fall of that same year, he presented a paper at the American Society for Quality Control-Energy Division's Annual Conference discussing the report. The report and the paper are remarkable in that, to the best of my knowledge, they are the only works of their kind. During a time when the use of quality assurance in scientific research and engineering development is more and more an enforced requirement, there is nothing that addresses the meaning of quality for the principal product of research and development: data. To be sure, here and there are bits and pieces, scattered throughout speeches presented at various qa gatherings, but there has been nothing comprehensive. Nothing, that is, until Wayne's work. It fills a gap and I hope that other publications will follow.

Following is a review of Wayne's report. Unless otherwise indicated, all the quotations, definitions, and page references are from the report.

Wayne proposes five quality characteristics of data as follows: (page 15)

> VALIDITY Data are valid when the methods, practices, techniques, and equipment used to obtain and treat them are technically sound, based on objectivity, and selected properly.
>
> INTEGRITY Data have integrity when methods, practices, techniques, and equipment have been used correctly and when data are free from tampering.
>
> RELIABILITY Data are reliable when there is adequate confidence that statistical inferences made, based on the data's precision, are correct.
>
> PRESERVATION Data are preserved when they are recorded and are protected from damage and unintentional destruction.
>
> RETRIEVABILITY Data are retrievable when they can be readily obtained from wherever stored.

These five characteristics are derived from the lifetime of data, which consists of four stages: preparation, generation, treatment, and use. (page 7).

During the preparation stage, one plans and organizes in order to select appropriate methods and the right equipment for obtaining the desired data. Using the selected methods and equipment to obtain and record data constitutes the generation phase. The reduction of data to reportable and usable levels is the third or treatment stage. And finally, the data are used.

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There are a number of fundamental requirements that belong to each of the four stages of the lifetime of data. Taken collectively this is what they look like. (page 11, Table 1).

a. Methods, practices, techniques, and equipment used to obtain and treat data must be:

   1) based on sound scientific and engineering principles,

   2) selected properly for a specific application, and

   3) used correctly.

b. The selection, application, and use of methods and equipment must be based on objective judgment, reasoning, and observations.

c. Data must be free from tampering.

d. The acquisition of data must be planned and the data generated must be analyzed, preferably using statistical techniques.

e. Data must be recorded in some way when generated.

f. Data must be protected from damage and unintentional destruction during their prescribed lifetime.

g. Data must be retrievable when needed.

To summarize. There is a lifetime of data, consisting of four phases. Attached to each phase are fundamental requirements. The four phases and the requirements lead to the five quality characteristics of data.

For a given body of data, when the methods whereby these data were derived is known and the quality characteristics of these data are established, one can accomplish two objectives. One, quality data can be obtained, and, two, it can be objectively shown that quality data has been obtained. In a slightly different context these two goals are expressed as the attainment of quality and the assessment that quality was attained. Attainment of quality is a continuous management process, which requires management principles that can be taught. Assessing that quality is obtained is part of the management "feedback loop" which is such a prominent part of management by quality assurance. Both require that one knows what has to be measured and that it can indeed be measured.

Wayne discusses the attainment of quality first. He begins by noting that the research and development process has developed various practices to control work in order "to avoid preventable mistakes, failures, and losses that adversely affect research and development work." (page 16). These practices are grouped into eight broad categories and summarized in a table (yes, Wayne does have a penchant for categorization and tables).

The first category is called "The Planning and Organization of Projects", (page 17). This category contains four individual practices which are discussed in the report. They are highlighted here.

1. Establishing Work Objectives.

   This is the most important part of planning. "A clear statement and understanding of the objectives is required. Particular emphasis should be given to assuring participation by all organizations and disciplines affected by or interfacing with the planned work. Appropriate review and approval should be obtained." (page 18).

2. Defining Work Tasks.

   Once it is known where one wishes to go, it is time to plan the ways to get there. "Practices for defining work tasks should include sufficient documentation and review/approval action to assure technical adequacy, identification of constraints, and description of any unusual or special requirements." (page 19). Work objectives and work tasks are normally written in a project plan.

3. Design of Experiment.

   "A good experimental design is one which furnishes the required information with the minimum of experimental effort. To do this three things are required: first, the questions to be answered by the experiments must be correctly formulated; second, a correct choice of experimental method must be made in the light both of the accuracy required and of the various experimental pitfalls which are likely to be encountered; and third, the general pattern of the experiments, i.e., the number, spacing, and interrelation of the individual observations, must be correctly chosen."[2]

4. Assignment of Responsibility.

   Responsibilities must be carefully assigned and clearly defined in writing. The assignment of responsibilities should be made known to all project participants. "Interfaces between associated organizations should be well established" (page 20). (Reviewer's Note: During the development of the LLNL QA Manual, it was concluded that responsibilities should be assigned in such a way that there are no overlapping assignments, nor gaps between assignments. The consequence of either may be devastating as can be read in some of DOE's accident investigation reports.)

The second broad category is called "Training and Qualification of Personnel". The two individual practices that make up this category are called, not surprisingly, training and qualification. (pages 20 and 21).

1. Training.

   Training is a basic management responsibility. It may cover a wide variety of efforts, from formal training programs, to informal ones, to on the job training. The extent of a training program is a function of the job requirements or the complexity of the job.

2. Qualification.

   Job qualification is also a management responsibility. Qualifications can be based on "education, experience, and job knowledge [all the way to] a formal system requiring passing tests and demonstrating proficiency in required job skills." (page 21).

The next category is "Preparation and Control of Procedures". (pages 21 and 22). Laboratory work consists of routine and non-routine activities. The non-routine "activities are initially planned, but are subject to changes as an experiment or study proceeds. Procedures are not normally prepared for such activities." (page 21).

Procedures are written for the routine activities. They are written to "control the processes and avoid errors leading to unsatisfactory results [and to] provide guides for those doing the work." (page 22). Procedures must be carefully prepared and controlled.

1. Preparation.

   Procedures must be "well-written, complete, and correct." (page 22). They should have a consistent format, and they should be reviewed for both technical content and management acceptance.

2. Control.

   Once procedures are released for use, they are controlled. This is to assure that time does not make procedures obsolete. Control of procedures requires a distribution system, a collection system, and systematic audits.

"Peer Review of Work" comes next. Peer review becomes particularly important when the work is new or advancing the state-of-the-art. The following individual practices are associated with peer review. (pages 23 and 24).

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1. Responsibility.

"Peer reviews should be planned and conducted by the organization responsible for the work. That organization is also responsible for following up on recommendations and comments coming from a peer review, including the verification and documentation that all issues raised have been addressed." (page 23).

2. Types.

Peer reviews are either formal or informal. Informal peer reviews are reviews of work by persons not involved in the work. They are or are not documented. "Formal peer reviews are characterized by the following: established experts outside and independent of the organization are used; a notification letter is issued identifying time, place and participants; a meeting is held in which presentations about the work are made to the participants; a detailed report of the review is issued; and a written response from the organization is required regarding recommendations and comments made by the reviewers." (page 23).

3. Use.

"Peer reviews should be used to evaluate project planning and to verify the technical adequacy of procedures and techniques, particularly when there is a unique application of an established standard technique." (page 24). They may also be used when a major project milestone is reached, or when a change with a potential major impact is contemplated.

4. Criteria.

"Peer reviews should be planned and conducted using the following criteria: reviewers are not directly involved with the work; reviewers have technical expertise in the field; reviewers are provided with sufficient information about work, including purposes and objectives, to adequately evaluate the work; and the results of the peer review are documented." (page 24).

5. Documentation.

"The extent of documentation should depend on the type of review." (page 24). It could range from merely signing a review sheet all the way to sufficient documentation so that a third party who was not present at the review can reconstruct down to any desired degree what happened during the review.

So far nothing concrete has happened. Halfway through the eight broad categories and no experiment has been run. Lots of planning, checks to make sure that the plans are correct, or at least as correct as is possible, but no actual experiment. The fifth category pertains to the actual running of the experiment. It is called "Acquisition, Protection, and Evaluation of Data." (page 25). This category is "crucial to research and development projects." (page 25). The practices and methods used to acquire, protect, and evaluate data are usually proven adequate through use throughout the scientific discipline. Nevertheless, whatever procedures are used, they should be identified and described each time they are used. This will accomplish at least two things. First persons who do the work have ready reference on how the work is to be done. Secondly, if mistakes are made, or data are lost, it is easier to retrace the steps of the work and identify where errors were made.

There are six individual practices associated with this category. Again, following are their highlights.

1. Technical Adequacy of Practices.

   The technical adequacy of practices is usually established by referencing work already done which is related to the work at hand. Peer review is another way to establish technical adequacy of practices. (page 25).

2. Control of Measuring and Test Equipment.

   This practice pertains to the selection, calibration, and correct use of measuring or test equipment.

3. Data Records.

   It is so obvious as to be almost trivial: data that are obtained must be recorded, otherwise they are lost. Data can be recorded on a variety of media but "provisions should exist to permit the recording of observations, ideas, or other kinds of information that the researcher or developer becomes aware of during an experiment or study, including changes made in steps taken and conditions used." (page 26).

4. Identification of Data.

   "Practices should be established to assure that all data are recorded so that they are clearly identifiable and traceable to the experiment, study, or project from which the data were produced. It is very important that this identification and traceability be maintained throughout the needed lifetime of the data." (page 26).

5. Control of Erroneous Data.

"Procedures are needed for controlling data that are erroneous, rejected, superseded, or otherwise unsuited for their intended use. The procedures should contain instructions for the identification, segregation, and disposition of inadequate data to avoid their inadvertent use." (page 27).

6. Evaluation.

"To insure that the best use can be made of experimental results, it is important to preplan or design the entire experimental program so the data, when collected, will be suitable for analysis by one of the standard statistical methods." (page 27).

Now data have reportable form: the next stage to be considered in the lifetime of data is their use. The use of data requires that records are kept. The keeping of records requires a record collection effort, a record retention effort, and a record retrieval effort. Wayne does not really recognize these three efforts as such. His is a different breakdown described in the sixth broad category, "Use and Control of Records." (page 27, 28, 29). There are four individual practices here.

1. Records System.

There should be a written description of the way in which an organization handles its records.

2. Record Validation.

"Data records may be subject to reviews and evaluations, which may occur several years after a record was produced. The authentication practices should result in records that are clearly traceable and identifiable as the valid product of the responsible organization, individual, or project." (page 28).

3. Records Identification, Indexing, and Retention.

"Practices of record identification should include sufficient information to permit identification of the record with the item or activity to which it applies." (page 29). In this section Wayne introduces the problem that sometimes arises with respect to raw data. Does one disregard the raw data once they have been reduced to reportable, or comprehensible, entities. What about erroneous data? Wayne states that "The availability of raw data can be important if a problem surfaces after the completion of a research or development project. That can be particularly true if the person who produced the data is no longer available." (page 29).

4. Records Distribution and Storage.

"The records management system should clearly define records distribution and handling practices. Individuals or the organizations responsible for distribution, receiving and storage of records should be identified." (page 29).

The next category is out of place. In developing the categories, the lifetime of data scheme was followed. With the data in records and handled in accordance with a records system and ready for use, there seems to be nothing left to worry about. Wayne has two more categories to go. The next, number seven, is called "Control and Handling of Equipment and Materials." (page 30). I am of the opinion that this category is part of either the preparation phase or the acquisition phase. Nevertheless, this is Wayne's report and he put it here. Five individual practices make up this category.

1. Maintenance of Equipment.

Equipment should be maintained. Defective equipment should be segregated from good equipment to prevent accidental use.

2. Calibration.

Equipment should be in calibration when used.

3. Quality of Materials.

Specifications describing the desired quality of materials should be written. Verification that the desired quality is present in the material should occur prior to use.

4. Labeling.

"Labels should include pertinent information relating to identity, composition, safety hazards, stability, and storage and handling requirements." (page 31).

5. Storage of Materials.

"Storage containers should protect materials from contamination by impurities and from change in concentration. Storage conditions should meet special requirements such as limits of exposure to light, humidity, and temperature." (page 31)

The last category is "Identification and Correction of Deficiencies". This category is also out of place here and would be better placed in the preparation phase. It has three individual practices.

1. Identification.

   Deficiencies should be recognized and promptly reported.

2. Evaluation.

   The root cause of reported deficiencies should be determined in order to prevent recurrence.

3. Correction and Follow-Up.

   Once the root cause of a deficiency is determined, a corrective action can be determined and implemented.

And so there you have it, Wayne's model. To summarize the entire model. The lifetime of data has four phases. Each phase has fundamental requirements associated with it. From the phases and their requirements the five quality characteristics of data are derived. Based on the five quality characteristics, practices are defined that establish and assure these quality characteristics. These practices are organized in eight broad categories.

Wayne spends one and one half pages of the report on the assessment of quality. It is not very comprehensive and it and the rest of the model can be summed up best by Table 4, "Laboratory Practices Relating to Quality Characteristics", which is reproduced at the end of this review.

What is the utility of Wayne's report? Assume for the sake of this argument that the model of the process he proposes is the correct one: that scientific data are created this way, that the quality characteristics are those he proposes, and the practices he describes are the ones that will result in data having the desired quality characteristics.

The model can then be used to plan for the quality of data. A manager, scientist or administrator, should insist that the steps of the model be followed. A manager would use the model in forming judgments on the adequacy of the control of experiments. Notice that most of the decisions are left up to the individual performing the experiment, but that the execution of those decisions are judged in terms of the model. Call this the forward use of the model. As the experiment is planned, executed, and controlled the model is applied.

The second use of the model perhaps could be called the reverse use. The end product of the process, data, is submitted for inclusion in the records as a quality assurance record. In order to qualify as a quality assurance record, the data must have the five quality characteristics. In order to establish whether or not the five quality characteristics are present, the process is retraced guided by the model and using the documents which were created when the model was executed.

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The quality of data is attained through the forward use of the model, assurance of the attainment can be objectively established through the model's reverse use. In ongoing projects, the two, attainment and assurance of attainment, occur simultaneously. Thus the model as a whole may be used to improve the process of obtaining data, i.e., improve the project.

REFERENCES

1. W. L. Devlin, Quality of Scientific and Engineering Data, HEDL-7471, Richland, WA, Westinghouse Hanford Company, 1984, 42 pages.

2. Owen L. Davies, Ed. The Design and Analysis of Industrial Experiments, New York, second edition, Hafner Publishing Co., reprinted 1967, cited by W. L. Devlin in Quality of Scientific and Engineering Data.

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TABLE 4. Laboratory Practices Relating to Quality Characteristics

	LABORATORY PRACTICES																														
	A				B		C		D					E						F				G					H		
CHARACTERISTICS	1	2	3	4	1	2	1	2	1	2	3	4	5	1	2	3	4	5	6	1	2	3	4	1	2	3	4	5	1	2	3
Validity	X	X					X		X	X	X	X	X	X	X														X	X	X
Integrity				X	X	X	X	X		X	X	X	X		X			X						X	X	X	X	X	X	X	X
Reliability	X	X	X	X			X								X			X	X						X	X			X	X	X
Preservation				X	X		X									X	X			X	X		X						X	X	X
Retrievability				X	X		X	X									X			X	X	X	X						X	X	X

A. Planning and Organization
1. Establishing Work Objectives
2. Defining Work Tasks
3. Design of Experiment
4. Assignment of Responsibility

B. Training and Qualification
1. Training
2. Qualification

C. Procedures
1. Preparation
2. Control

D. Peer Review
1. Responsibility
2. Types
3. Use
4. Criteria
5. Documentation

E. Acquisition, Protection and Evaluation of Data
1. Technical Adequacy of Practices
2. Control of M&T Equipment
3. Data Records
4. Identification of Data
5. Control of Erroneous Data
6. Evaluation

F. Use and Control of Records
1. Records System
2. Record Validation
3. Record Ident., Indexing and Retention
4. Record Distribution and Storage

G. Control and Handling of Equipment and Materials
1. Maintenance of Equipment
2. Calibration
3. Quality of Chemicals
4. Labeling
5. Storage of Materials

H. Ident. & Correction of Deficiencies
1. Identification
2. Evaluation
3. Correction and Follow-up

AUDIT CHECKLIST NO. 85-6 AUDIT NO. 85-6 PAGE 1 OF PAGE 77

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
This checklist is based on NNWSI NVO-196-17, Rev. 3 and its SOP's. 1. Organization A. The following are documented for all activities affecting quality: (1) Organizational Structure (a) Organizational structure and responsibility assignments are such that: 1) Quality is achieved and maintained by those responsible for performing the work; and 2) Quality achievement is verified (documented) by persons or organizations not directly responsible for performing the work. (b) Functional responsibilities. (c) Levels of authority. (d) Lines of communication. (e) Responsibility and authority of each organization involved. (f) Interface control - external interfaces between organizations and internal interfaces between organizational units, and changes thereto, with interface responsibilities defined.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
B. Persons or organizations responsible for assuring establishment of the QA program and for verifying that activities affecting quality have been correctly performed are identified and have sufficient authority, access to work areas, and organizational freedom to: (1) Identify quality program; (2) Initiate, recommend, or provide solutions to quality problems; (3) Verify implementation of solution; and (4) Assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. Responsibility for this function is designated in writing. C. Persons or organizations responsible for establishment of QA and verifying correct performance of activities affecting quality: (1) Have direct access to responsible management; (2) Report to a management level such that required authority and organizational freedom are provided; (3) Have sufficient independence from cost and schedule considerations;				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(4) May delegate work provided interface controls are defined and documented, but retain responsibility for the work.				
D. Management participation and support of the program is established.				
2. Quality Assurance Program				
A. The program provides for obtaining WMPO/NV acceptance of proposed changes to the program or supporting procedures before putting changes in effect.				
B. The program includes a commitment that any development, control, and/or use of computer programs will be conducted in accordance with the QA Program.				
C. The Program is planned, implemented, and maintained in accordance with supporting procedures identified in the Program.				
D. The Program identifies the activities and items to which it applies.				
E. The Program includes consideration of the technical aspects of activities affecting quality.				
F. The Program provides control over activities affecting quality levels I, II, and III related to radiological health and safety importance.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
G. The Program provides for planning and accomplishment of activities affecting quality under controlled conditions which include: (1) Use of appropriate equipment; (2) Suitable environmental conditions; and (3) Assurance prerequisites for activity are satisfied. H. The Program provides for any special controls, processes, test equipment, tools, and skills needed to attain required quality and for verification of quality. I. Management of those organizations implementing the QA Program, or portions thereof, regularly assesses adequacy of part of Program for which responsible and assures its effective implementation: (1) What organizations are responsible? (2) Who is management? (3) What are the frequency and means of assessment and assurance of effective implementation? (4) How is action documented?				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
J. Program provides for indoctrination and training, as necessary, of personnel performing activities affecting quality to assure suitable proficiency is achieved and maintained: (1) Personnel performing activities affecting quality are identified. (2) Inspection and Test requirements are defined. (3) Documentation requirements are defined. (4) Performance is evaluated to determine a need for retraining (not to exceed one (1) year). K. Qualification requirements for inspection and test personnel (except NDE): (1) Activities that require qualified inspection and test personnel are designated by the responsible organization. (2) Minimum requirements for inspection and test personnel are designated. (3) Program provides for establishment and use of written procedures for such qualification. (4) Program assures that only qualified personnel are permitted to perform inspection and test activities.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(5) Program includes provision for indoctrination of personnel on technical objectives and requirements of applicable codes, standards, and QA Program elements.				
(6) Formal training, as needed, is conducted to qualify personnel who perform inspections and tests.				
(7) On-the-job training is included in program with emphasis on actual performance of inspections and tests.				
(8) Initial capabilities for certification are based on evaluation of candidate's education, experience, training, and either results or capability demonstration.				
(9) Job performance is reevaluated:				
(a) At periodic intervals not to exceed three years;				
(b) By evidence of continued satisfactory performance or redetermination of capability as required for initial capability for certification.				
(10) Program provides for removal of personnel from activity if determined by responsible organization that an individual's capabilities are not in accordance with specified qualification requirements.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(11) Program requires reestablishment of required capability if person has not performed inspection and test activities in his qualified area for one year or more.				
(12) The qualification of personnel is certified in writing on a form that includes the following information:				
(a) Employer's name;				
(b) Identification of person being certified;				
(c) Activities certified to perform;				
(d) Basis used for certification, including such factors as:				
1) Education, experience, and training;				
2) Test results, where applicable;				
3) Results of capability demonstration;				
(e) Results of periodic evaluation;				
(f) Results of physical examinations, when required;				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(g) Signature of employer's designated representative responsible for certification;				
(h) Date of certification and date of certification expiration.				
(13) Program provides for identification of special physical characteristics needed for requirements for initial and subsequent physical examinations.				
(14) Records of personnel qualification are established and maintained by the employer.				
L. Qualification requirements for QA Program audit personnel.				
(1) Audit personnel qualifications and requirements for use of technical specialist for auditing QA program is established:				
(a) Program provides for assigned personnel to have experience or training equivalent to scope, complexity, or special nature of the activities to be audited.				
(b) Program provides for development of auditor competence by:				
1) Orientation				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
2) Training - general and specialized 3) On-the-job training, guidance, and counseling under direct supervision of a Lead Auditor. (2) Lead Auditor qualification (a) Requirements as follows are satisfied for Lead Auditor before designation as such: 1) Communication skills - capability to communicate effectively in writing and orally is attested to in writing by the employer. 2) Training - to extent necessary to assure competence in auditing skills: a) Knowledge and understanding of Code and referenced documents b) General structure of QA Program as a whole and applicable elements as defined in the Code c) Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying, following up on corrective action, and closing out audit findings				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
d) Audit planning e) On-the-job training. (3) Audit participation - five QA audits in three years with one being a nuclear QA audit within one year of qualification certification. (4) Examination - pass oral, written, practical, or combination. a) Employer is responsible for development and administration of examination in conformance with Code requirements. b) Employer assures integrity of examination. c) Employer retains objective evidence regarding types and content of examination. (3) Maintenance of qualification (a) Proficiency if maintained through: 1) Regular and active participation in audit process. 2) Review and study of Code, standards, procedures, instructions, and other				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
documents related to QA Program and auditing, and 3) Participation in training programs. (b) Management performs annual assessment and extends qualification, requires retraining or requires requalification. (c) Management documents annual assessments and resultant action. (d) Requalification is required for Lead Auditors who fail to maintain proficiency for two years or more. (e) Requalification includes retraining and reexamining as required for initial qualification and participation as an auditor in at least one nuclear QA audit. (4) Administration of audit program (a) Employer is responsible for training of auditors. (b) Selected audit personnel are independent of direct responsibility for performance of activities which they audit.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(c) The Lead Auditor, prior to commencing audit, concurs that assigned personnel collectively have required experience or training for activities to be audited.				
(5) Records				
(a) Personnel qualification records for auditors and Lead Auditors performing audits are established and maintained by the employer.				
(b) Certification of qualification				
1) Each Lead Auditor is certified by his employer as being qualified to lead audits.				
2) Certification of qualification as minimum documents the following:				
a) Employer's name				
b) Lead Auditor's name				
c) Date of certification or recertification				
d) Basis of qualification				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
e) Signature of employer's designated representative responsible for certification 3) Records for each Lead Auditor are maintained and updated annually. M. Qualification requirements for NDE personnel (when required) (1) Qualification requirements are satisfied for all persons performing required NDE. (2) Qualification of subcontractor personnel are verified by the organization subcontracting for the service. (3) NDE personnel are qualified to employer's written practice which includes the SNT-TC-1A-1980 requirements as minimum with modifications as follows: (a) Qualification of Level III NDE personnel is by examination. 1) Basic and method examinations are prepared and administered by employer, ASNT, or outside agency. 2) Specific examination is prepared and administered by the employer or an outside				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
agency. The written practice identifies minimum grade requirements. The minimum grade for the specific examination is not less than 80% when ASNT has administered the basic and method examinations. (b) The written practice required by SNT-TC-1A and procedures used for examination of personnel are referenced in the employer's quality program. (c) Reduction in time and experience based on limited operations performed or limited scope are described in the written practice, and limitations or restrictions placed on the certification are described in the written practice and on the certificate. (d) Jaeger Number 1 or equivalent letters are used for the visual examination. (e) Limitations on Level I activities are included in the written practice. (4) Personnel are qualified to comparable levels of competency by subjection to comparable examination for NDE methods not covered by SNT-TC-1A. (5) Emphasis is on individual's ability to perform NDE in accordance with applicable procedure for intended application.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(6) Certification of personnel				
(a) Employer retains responsibility for adequacy of Program and is responsible for certification of Levels I, II, and III NDE personnel.				
(b) Employer has letter from ASNT as basis for certification when ASNT is outside agency administering Level III basic and method examinations.				
(c) Employer records include examination results when an outside agency is the examining agent for Level III qualification of employer's personnel.				
(7) Personnel qualification records for NDE personnel identified in SNT-TC-1A are retained by the employer.				
3. Design and Site Investigation Control				
A. Design is defined, controlled, and verified.				
B. Design interfaces are identified and controlled.				
C. Design adequacy is verified by persons other than those who designed the item.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
D. Design changes, including field changes, are governed by control measures applied to the original design.				
E. Design documents are verified for adequacy and compliance with the design requirement, regulatory guides, and other documents from which the design is based.				
F. Design inputs are				
(1) Identified and documented and their selection is reviewed and approved by the responsible design organization;				
(2) Specified and approved on a timely basis to level of detail necessary to permit design activity to				
(a) be carried out in correct manner,				
(b) provide consistent basis for making design decisions, accomplish design verification measures, and evaluate design changes;				
(3) translated correctly into design documents.				
(4) Changes, including reasons for changes, are identified, approved, documented and controlled.				
G. Design process				
(1) Responsible design organization prescribes and documents design activities on timely basis to				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(a) Permit design process to be carried out correctly, (b) Permit verification that design meets requirements; (2) Quality standards are identified and documented and their selection is reviewed and approved; (3) Changes from specified quality standards, including reasons for the changes, are identified, approved, documented, and controlled; (4) Design methods, materials, parts, equipment, and processes essential to function of item are selected and reviewed for suitability of application; (5) Applicable documented information derived from experience is made available to cognizant design personnel; (6) Final approved design is relatable to design input by documentation in sufficient detail to permit design verification and identification of assemblies and/or components that are part of the item being designed.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
H. Design analyses are				
(1) Performed in planned, controlled, and documented manner;				
(2) Legible and in a form suitable for reproduction, filing, and retrieval;				
(3) Detailed as to purpose, method, assumptions, design input, references, and units such that a qualified person can review, understand, and verify results without recourse to originator;				
(4) Calculations are identifiable by subject, originator, reviewer, and date; or other data such that calculations are retrievable;				
(5) Documentation of design analyses includes				
(a) Definition of objective of the analyses,				
(b) Definition of design inputs and their sources,				
(c) Results of literature searches or other background data,				
(d) Identification of assumptions and indication of those that must be verified as design proceeds,				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(e) Identification of computer calculation types, code or programming inputs, outputs, and code or program validation.				
(f) Review and approval.				
I. Design verification				
(1) Design documents are verified for adequacy and compliance with the design requirements, regulator guides, and other documents from which the design is based.				
(2) Adequacy of design is verified by design control measures such as one or more of the following:				
(a) Performance of design reviews,				
(b) Use of alternate calculations,				
(c) Or performance of qualification tests.				
(3) Responsible design organization identifies and documents the particular design verification method(s) used.				
(a) Are details of methods defined and documented, such that all applicable elements listed in NVO-196-17, Rev. 3, are addressed?				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(b) Are results of design verification clearly documented with identification of the verifier clearly indicated?				
(c) Does program provide for documenting the method of assuring that individual(s) or group(s) is competent?				
(d) Is individual(s) or group(s) performing verification other than those who performed the original design? Note: Cursory supervisory reviews do not satisfy intent of this requirement.				
(4) Does program provide for design verification of changes to previously verified designs, including evaluation of the effects of those changes on the overall design?				
J. Change control				
(1) Changes to final designs, including field changes, are justified and subjected to design control measures commensurate with those applied to original design.				
(2) Changes are approved by same affected groups or organizations which reviewed and approved original design documents.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(3) Design process and verification procedures are reviewed and modified as necessary where a design change is necessary because of an incorrect design.				
K. Interface control				
(1) Design interfaces are identified and controlled.				
(2) Design efforts are coordinated among participating organizations.				
(3) Interface controls include assignment of responsibility and establishment of procedures among participating organizations for preparation, review, approval, release, distribution, and revision of documents involving design interfaces.				
(4) Measures are established to provide QA review of design documents to assure they are prepared, reviewed, and approved in accordance with defined procedures.				
(5) Design information transmitted across interfaces is documented and controlled.				
L. Documentation and records				
(1) Design documentation and records, which provide evidence of compliance with safety-related				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
activities, are collected, stored, and maintained in accordance with documented procedures. (2) Documentation includes final design documents, such as drawings and specifications and revisions thereto and documentation which identifies the important steps, including sources of design inputs, that support the final design. 4. Procurement Document Control Note: Supplier as used in this checklist includes all vendors performing safety-related functions, such as subcontractors of services, material manufacturers, and material suppliers. A. Procurement documents for items and services include: (1) Applicable design basis and other requirements necessary to assure quality. (a) Technical requirements are specified, where necessary, by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions including revisions. (2) Provisions for idehtification of test, inspection, and acceptance requirements of the purchaser for monitoring and evaluating supplier's performance.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(3) Requirement that supplier have a quality assurance program consistent with requirements of NNWSI NVO-196-17, Rev. 3, as applicable. (a) Supplier required to incorporate appropriate QA program requirements in subtier procurement documents. (b) Requirement for review and approval of suppliers QA program prior to initiation of activities. (4) Right of access by purchaser or others authorized by purchaser to supplier facilities and records. (5) Documentation requirements (a) Documentation to be submitted for information, review, or approval by purchaser. (b) Time of submittal. (c) Purchaser requires supplier to maintain QA records for the retention times specified in disposition requirements. (d) Requirements for reporting and approving disposition of nonconformance.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
B. Procurement Document Review (1) Reviews of procurement documents and changes are: (a) Made to assure inclusion of appropriate provisions to assure items or services will meet the specified requirements; (b) Documented to provide objective evidence prior to contract award. (2) Changes made as a result of bid evaluation or precontract negotiations and incorporated into the procurement documents. (a) Review of changes and effects are completed prior to contract award. (b) Review includes the following considerations: 1) Inclusion of appropriate requirements in procurement documents; 2) Determination of additional or modified design criteria; 3) Analysis of exceptions or changes requested by supplier.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(3) Reviews are performed by personnel with:				
(a) access to pertinent information;				
(b) understanding of requirements and intent of the procurement documents.				
C. Procurement Document Changes				
(1) Changes are subject to same control as utilized in preparation of original documents.				
5. Instructions, Procedures, and Drawings				
A. Activities affecting quality are prescribed by and performed in accordance with documented instructions, procedures, or drawings.				
B. Instructions, procedures, and drawings include or reference acceptance criteria for determining that prescribed activities have been satisfactorily accomplished				
6. Document Control				
A. Documents are controlled to assure that correct and applicable documents are available at the location where they are used.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
B. Document control provides for the following: (1) Identification of documents to be controlled; (2) Identification of personnel, positions, or organizations responsible for: (a) Preparing (b) Reviewing (c) Approving (d) Issuing (3) Review of documents for adequacy, completeness, and correctness prior to approval and issuance. C. A master list or equivalent document control system is established to identify the current revision of documents (reports, instructions, procedures, specifications, drawings, etc.). D. Document changes (1) Major changes are reviewed and approved by the same organization that performed original review and approval unless other organization designated.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(2) The organization that reviews major changes has access to background data or information upon which to base approval.				
(3) Minor changes to documents are changes such as inconsequential editorial corrections. (Not mandatory).				
(a) The type of minor changes that do not require review and approval are clearly delineated.				
(b) The persons who can authorize minor changes without a review and and approval are clearly delineated.				
(c) All other changes are treated as major changes.				
(4) Documents released prior to review are so identified.				
(5) Procedures are established and described to assure that obsolete or superseded documents are removed and replaced by applicable revisions in work areas in a timely manner.				
7. Control of Purchased Materials, Equipment, and Services				
A. Controls				
(1) Assure conformance with specified requirements				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(2) Provide for the following as appropriate				
(a) Source evaluation and selection				
(b) Evaluation of objective evidence of quality furnished by the supplier				
(c) Source inspection				
(d) Audit				
(e) Examination upon delivery or completion				
B. Procurement Planning				
(1) Activities are planned and documented to assure systematic approach.				
(2) Procurement methods and organizational responsibilities are documented.				
(3) Planning determines				
(a) what is to be accomplished				
(b) who is to accomplish it				
(c) how it is to be accomplished				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(d) when it is to be accomplished.				
(4) Planning is accomplished early, no later than at start of procurement activities required to be controlled, to assure interface compatibility and uniform approach to procurement process.				
(5) Planning results in				
(a) documented identification of methods to be used in procurement activities				
(b) documented sequence of actions and milestones indicating completion of activities				
(c) preparation of applicable procedures prior to initiation of each activity listed in (6) below.				
(6) Planning provides for integration of				
(a) procurement document preparation, review, and change control				
(b) selection of procurement sources				
(c) bid evaluation and award				
(d) purchaser control of supplier performance				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(e) verification activities by purchaser, including notification for hold and witness points				
(f) control of nonconformance				
(g) corrective action				
(h) acceptance of item or service				
(i) quality assurance records.				
C. Supplier Selection				
(1) Selection is based on evaluation of supplier capability to provide items or services to requirements of procurements prior to award of contract.				
(2) Procurement source evaluation and selection measures are implemented by purchaser.				
(3) Purchaser's organizational responsibilities for determining supplier capability are identified.				
(4) Measures for evaluation and selection of procurement sources, and results therefrom, are documented and include one or more of the following:				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(a) evaluation of supplier's history of providing an identical or similar product and current capability;				
(b) supplier's current quality records supported by documented qualitative and quantitative information which can be objectively evaluated;				
(c) supplier's technical and quality capability as determined by a direct evaluation of his facilities and personnel and the implementation of his quality assurance program.				
D. Bid Evaluation				
(1) Bid evaluation:				
(a) determines extent of conformance to procurement documents.				
(b) is performed by individuals or organizations designated to evaluate the following subjects as applicable to type of procurement:				
1) technical considerations				
2) quality assurance requirements				
3) supplier's personnel				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
4) supplier's production capability 5) supplier's past performance 6) alternates 7) exceptions. (2) Unacceptable quality conditions resulting from bid evaluation are resolved, or commitments to resolve are obtained, prior to contract award. E. Supplier Performance Evaluation (1) Measures are established for purchaser (a) to interface with the supplier (b) to verify supplier's performance. (2) The measures include: (a) establishing an understanding between purchaser and supplier of provisions and specifications of the procurement documents; (b) requiring the supplier to identify planning techniques and processes to be utilized in fulfilling procurement document requirements;				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(c) reviewing supplier documents which are generated or processed during activities fulfilling procurement requirements; (d) identifying and processing necessary change information; (e) establishing a method of document information exchange; (f) establishing extent of source surveillance and inspection activities. (3) Verification activities are conducted as early as practical. (4) Purchaser's verification activities do not relieve the supplier of his responsibilities for verification of quality achievement. (5) Extent of activities (a) The extent of verification activities, including planning is a function of relative importance, complexity, and quantity of the time or services procured and the supplier's quality performance. (b) Verification activities are accomplished by qualified personnel assigned to check, inspect, audit, or witness activities of suppliers.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(6) Records (a) Activities performed to verify conformance to requirements of procurement documents are recorded. (b) Source surveillance and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions are documented. (c) Purchaser assures documentation is evaluated to determine the effectiveness of the supplier's quality assurance program. F. Control of Supplier-Generated Documents (1) Supplier-generated documents are controlled, handled, and approved in accordance with established methods. (2) Means are implemented to assure that supplier document submittal is accomplished in accordance with procurement document requirements. (3) Measures provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data against acceptance criteria.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
G. Control of Changes in Items or Services				
(1) Measures to control changes in procurement documents are established, implemented, and documented.				
H. Acceptance of Item or Service				
(1) General				
(a) Methods are established for acceptance of items or services being furnished by the supplier.				
(b) Supplier is required to verify that item or service being furnished complies with procurement requirements.				
(2) Methods of acceptance (as appropriate)				
(a) Methods used to accept item or related service are as follows:				
1) Certification of Conformance				
a) Certificate identifies purchased material or equipment.				
b) Certificate identifies specific procurement requirements met including approved changes, waivers, or deviations.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
c) Certificate identifies requirements not met with explanation and means for resolution.				
d) Certificate is attested to by person responsible for this QA function - function and position are described in the purchaser's or supplier's QA Program.				
e) Certification system is described in QA Program.				
f) Means are provided to verify validity of supplier certificates and effectiveness of certification system.				
2) Source verification				
a) It is performed at intervals consistent with importance and complexity of item or service.				
b) It is implemented to monitor, witness, or observe activities.				
c) It is implemented with plans to perform inspections, examinations, and tests at predetermined points.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
d) Documented evidence of acceptance by purchaser is furnshed to the receiving destination of item, purchaser, and supplier.				
3) Receiving Inspection				
a) Includes inspection of purchased items as necessary to verify conformance to specified requirements.				
b) Takes into account source verification and audit activities and demonstrated quality performance of supplier.				
c) Is performed to established procedures and inspection instructions to verify by objective evidence such features as:				
1) Proper configuration				
2) Identification				
3) Dimensional characteristics				
4) Physical and other characteristics				
5) Freedom from damage				
6) Cleanliness				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
d) Is coordinated with review of supplier documentation.				
4) Post-installation testing				
a) Test requirements and acceptance documentation is mutually established by purchaser and supplier.				
(3) Acceptance of services only (consulting, engineering, third party inspection, etc.)				
(a) Purchaser accepts service by any or all of following methods:				
1) Technical verification of data produced				
2) Surveillance and/or audit of the activity				
3) review of objective evidence for conformance to procurement document requirements such as certifications, design reports, etc.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
I. Control of supplier nonconformances (1) Methods for disposition of items and services that do not meet procurement document requirements are established and documented by the purchaser and supplier. (2) Methods of disposition contain provisions as follows: (a) evaluation of nonconforming items (b) submittal of nonconformance notice to purchaser by supplier as directed by purchaser with supplier - recommended disposition and technical justification. (c) Purchaser approval of recommended disposition is required for nonconformance which consists of one or more of following: 1) Technical or material requirement is violated 2) Requirement in supplier documents, which have been approved by the purchaser, is violated 3) Nonconformance cannot be corrected by continuation of the original manufacturing process or by rework				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
4) The item does not conform to original requirements. (d) Purchaser disposition of supplier recommendation. (e) Verification of the implementation of the disposition. (f) Maintenance of records of supplier-submitted nonconformance. 8. Identification and Control of Materials, Parts, and Components A. Controls are established to assure that only correct and accepted items and samples are used or installed. B. Identification is maintained either on the items or in documents traceable to the items. C. Identification methods (1) Item identification (a) is included and maintained from initial receipt and fabrication up to and including installation				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(b) relates an item to an applicable design or other specifying document.				
(2) Physical identification				
(a) Physical identification is used to maximum extent possible.				
(b) Where physical identification on the item is impractical or insufficient, physical separation, procedural control, or other appropriate methods are employed.				
(3) Markings				
(a) Identification markings				
1) provide clear and legible identification				
2) do not detrimentally affect function or service.				
(b) Markings are transferred to each part of an identified item when subdivided.				
(c) Markings are not obliterated or hidden unless other means of identification are substituted.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
D. Specific requirements (1) Identification and traceability of items (a) Program is designed to provide identification and traceability control to appropriate documentation such as drawings, specifications, drilling logs, test records, NCRs etc. (2) Limited life items (a) Items which have limited calendar or operating life or cycles are identified and controlled to preclude use of items whose shelf life or operating life has expired. (3) Maintaining identification of stored items (a) Provisions are made for control of item identification consistent with planned duration and conditions of storage, such as: 1) Provisions for maintenance or replacement of markings and identification records 2) Protection of identification on items subject to deterioration due to environmental exposure 3) Provision for updating existing records.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
9. Control of Processes				
A. Process control documents, instructions, procedures, drawings, checklists, travelers or other appropriate documents.				
B. Process controls assure that process parameters are controlled and that specified environmental conditions are maintained.				
C. Processes affecting quality of items or services are described. As complete a listing as possible is provided of special processes, which are generally those processes where direct inspection is impossible or disadvantageous.				
D. Special Processes				
(1) Organizational responsibilities including those for QA are described for qualification of special processes equipment and personnel.				
(2) Special processes are performed in accordance with instructions which include or reference procedure, personnel, and equipment qualification requirements.				
(a) Organization performing the process is responsible for adhering to the approved procedures and processes.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
1) Qualification of personnel, procedures, and equipment comply with specified requirements.				
2) Conditions necessary for accomplishment of the process are included in procedures or instructions.				
3) Conditions in procedures or instructions include proper equipment, controlled parameters of process, and calibration requirements.				
(3) Acceptance criteria are specified or referenced in the process procedures or instructions.				
(4) Records are maintained for currently qualified personnel, processes, and equipment of each special process.				
10. Inspection				
A. Process sheets, travelers, or checklists are prepared that include the following:				
(1) Document numbers and revision to which the examination or test is to be performed				
(2) Space for recording results of examination and tests				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(3) Space for a signature, initials, or stamp and date activity was performed by the organizations' representative				
(4) Process sheets are reviewed by QA to ensure all necessary inspections are identified.				
B. Mandatory hold points at which witnessing is required by the organizations' representative are indicated in the process controlling documents, such as the traveler.				
C. Work does not proceed beyond mandatory hold points without consent of the organizations' representative, as appropriate.				
(1) Consent to waive specified hold points is recorded prior to continuation of work beyond the designated hold point.				
D. Characteristics to be inspected and inspection methods to be employed are specified on Process documents.				
E. Inspection is performed by QA personnel; when inspection requires special expertise, other individuals may be used, provided independence of the inspection function is maintained.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
F. Personnel				
(1) Inspection personnel do not report directly to immediate supervisors responsible for performance of work being inspected.				
(2) Each person who verifies conformance of work activities for purposes of acceptance is qualified to perform the assigned inspection task.				
(3) The qualification program and qualification of inspectors shall be documented and kept current.				
G. Inspection Planning (Procedures)				
(1) Planning is accomplished and documented.				
(a) The documentation identifies				
1) characteristics and activity				
2) methods of inspection				
3) acceptance/rejection criteria				
4) special measuring and test equipment, including accuracy required.				
(b) The documentation provides for recording objective evidence of inspection results.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(2) Sampling inspection, if used, is based on recognized standard practices.				
H. In-Process Inspection				
(1) Inspection is performed for work activities where necessary to verify quality.				
(2) Indirect control by monitoring of processing methods, equipment, and personnel is provided where inspection of processed items is impossible or disadvantageous.				
(3) Both inspection and process monitoring are provided when control is inadequate without both.				
(a) When used in combination, performance is in systematic manner to assure specified requirements for control of process and quality are achieved throughout duration of process.				
(b) Controls are established and documented for coordination and sequencing of activities at established inspection points during successive stages of the conducted process or construction.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
I. Final Inspections				
(1) Final inspections include a record review of results and resolution of nonconformances identified by prior inspections.				
(2) Final inspections are planned to arrive at conclusions regarding conformance to specified requirements.				
(3) Completed items are inspected for				
(a) completeness				
(b) calibration				
(c) markings				
(d) adjustments				
(e) protection from damage				
(f) other characteristics as required to verify quality and conformance of items to specified requirements.				
(4) Quality records are examined for adequacy and completeness or verified to have been so examined.				
(5) Acceptance of the item is documented and approved by authorized personnel.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(6) Modifications, repairs, or replacements of items performed subsequent to final inspection require reinspection or retest to verify acceptability.				
J. Inspection records, as a minimum, identify:				
(1) item inspected				
(2) date of inspection				
(3) inspector				
(4) type of observation				
(5) document numbers and revisions to which the examination, test, or inspection is performed				
(6) results or acceptability				
(7) reference to information or action taken in connection with nonconformance.				
11. Test Experiment Control				
A. Tests are planned and executed.				
B. Characteristics to be tested and test methods to be employed are specified.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
C. Test results are documented and their conformance with acceptance criteria evaluated.				
D. Test requirements and acceptance criteria are provided or approved by the organization responsible for the design of the item to be tested unless otherwise designated.				
E. Required tests are controlled.				
F. Test requirements and acceptance criteria are based upon specified requirements contained in design or other technical documents.				
G. Test procedures include or reference test objectives and provisions for assuring:				
(1) that applicable prerequisites for the test have been met:				
(a) calibrated instrumentation				
(b) appropriate equipment				
(c) trained personnel				
(d) condition of test equipment and item to be tested				
(e) suitable environmental conditions				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(f) provisions for data acquisition				
(2) that adequate instrumentation is available and used				
(3) that necessary monitoring is performed				
(4) that suitable environmental conditions are maintained.				
H. Documents used in lieu of written test procedures such as ASTM methods, approved drawings, etc. include adequate instructions to assure the required quality of work.				
I. Test results are documented and evaluated by a responsible authority to assure test requirements have been satisfied.				
J. Test records, as a minimum, identify				
(1) item tested				
(2) date of test				
(3) tester or data recorder				
(4) type of observation				
(5) results and acceptability				
(6) action taken in connection with any deviation noted				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(7) test procedure and revision (8) person evaluating test results. K. Experiment Control - Experiments shall be controlled by the use of logbooks and/or procedures (or other suitable means to provide uniform documentation of the experiment). The documentation shall include but is not limited to entries listed in paragraph 11.2.5.1 and 11.2.5.2 of NNWSI NVO-196-17, SOP-02-01. The following entries are made initially and as the experiment changes dictate: (1) Title of the experiment (2) Name of qualified individual(s) performing the experiment (3) Experiment objectives (4) Equipment and materials used (5) Calibration requirements The following entries are made daily or as appropriate: (1) Data and name of individual making the entry				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(2) Description of the experiment element attempted				
(3) Conditions which may adversely affect the experiment				
(4) Identification of samples used				
(5) Brief listing of results with notation of unaccepted results				
(6) Any deviation to the experiment				
(7) Interim conclusions reached if appropriate				
(8) Final results and a summary of the outcome of the experiment objectives previously listed.				
12. Control of Measuring and Test Equipment				
A. Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality are described, controlled, and, at specified periods, calibrated and adjusted to maintain accuracy within necessary limits.				
B. Selection of measuring and test equipment is controlled to assure they are of proper type, range, accuracy, and tolerance to accomplish function.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
C. Calibration and Control (1) Measuring and test equipment is calibrated, adjusted, and maintained at prescribed intervals, or prior to use, against certified equipment having known valid relationships to nationally recognized standards. (If no nationally recognized standards exist, the basis for calibration is documented.) Responsibilities for implementation are described. (2) In addition, calibration is performed when accuracy of device is suspect. (3) The method and interval of calibration for each device is defined. (4) When measuring and test equipment is found to be out of calibration (a) an evaluation is made and documented of validity of previous inspection or test results and acceptability of items previously inspected or tested (b) out-of-calibration devices are tagged or segregated and not used until recalibrated (c) devices consistently found out of calibration are repaired or replaced.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(5) Methods, frequency, and responsibility of periodic checking are included in QA program description.				
D. Measuring and test equipment is properly handled and stored to maintain accuracy.				
E. Records are maintained and equipment is marked to indicate calibration status.				
13. Handling, Storage, and Shipping				
A. Handling, storage, cleaning, packaging, shipping, and preservation of items are controlled to prevent damage or loss and to minimize deterioration by environmental conditions such as temperature and humidity.				
B. Handling, storage, and shipping of items are conducted in accordance with established work and inspection instructions, or other pertinent documents or procedures specified for use.				
C. Special equipment and special protective environments are specified and provided and their existence verified when required for particular items.				
D. Specific procedures are used for handling, storage, packaging, shipping, and preservation when required for critical, sensitive, perishable, or high-value items.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
E. Operators of special handling and lifting equipment are experienced or trained in use of equipment.				
F. Marking and labeling instructions for packaging, shipment, handling, and storage of items are established.				
14. Inspection Test, and Operating Status				
A. Status of inspection and test activities are identified either on the items or in documents traceable to the items to assure:				
(1) required inspections and tests are performed				
(2) items which have not passed the required tests and inspections are not inadvertently installed or used.				
B. Status is maintained through indicators:				
(1) physical location and tags				
(2) markings				
(3) shop travelers				
(4) stamps				
(5) inspection records				
(6) other suitable means.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
C. The authority for application and removal of status indicators is specified.				
15. Nonconformances				
A. Items that do not conform to specified requirements are controlled to prevent inadvertent installation or use.				
B. Controls provide:				
(1) identification				
(2) documentation				
(3) evaluation				
(4) segregation when practical				
(5) disposition of nonconforming items				
(6) notification to affected organizations.				
C. Identification				
(1) Identification of nonconforming items is by:				
(a) markings				
(b) tagging				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(c) other methods which do not adversely affect the use of item. (2) Identification is legible and easily recognizable. (3) Where identification of each item is not practical, the container, package, or segregated storage area, as appropriate, is identified. D. Segregation (1) Nonconforming items are segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned. (2) When segregation is impractical or impossible due to physical conditions, such as size, weight, or access limitations, other precautions are employed to preclude inadvertent use of a nonconforming item. E. Disposition (1) Control (a) Nonconforming characteristics are reviewed and recommended dispositions are proposed and approved in accordance with documented procedures.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(b) Further processing, delivery, installation, or use of nonconforming items are controlled pending an evaluation and an approved disposition by authorized personnel. (2) Responsibility and authority for evaluation and disposition of nonconforming items is defined. (3) Personnel performing evaluations to determine a disposition: (a) have demonstrated competence in the specific area they are evaluating (b) have an adequate understanding of the requirements (c) have access to pertinent background information. (4) Final disposition is repair or reject and is identified and documented. (Repair is the process of physically restoring a nonconformance to a condition such that an item complies with specified requirements.) (5) Technical justification for acceptability of nonconforming item, dispositioned repair, is documented.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(6) Repaired items are examined in accordance with applicable procedures and with the original acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria that comply with the specified requirements.				
F. QA responsibilities related to the nonconformance control system are described.				
G. Nonconformance reports are periodically analyzed by QA to show trends and significant results are reported to upper management for review and assessment.				
16. Corrective Action				
A. Corrective action requirements extend to the performance of subcontractor's corrective action measures.				
B. Conditions adverse to quality are identified promptly and corrected as soon as practical.				
C. In the case of a significant condition adverse to quality				
(1) cause of condition is determined				
(2) corrective action is taken to preclude recurrence				
(3) the identification, cause, and corrective action are documented and reported to appropriate levels of management				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(4) follow up action is taken to verify implementation of corrective action.				
D. Controls, documentation required including reviews and approvals, and identification of appropriate levels of management are included in the written description of the Quality Program.				
17. Quality Assurance Records				
A. Records that furnish documentary evidence of quality are indexed, specified, prepared, and maintained.				
B. Requirements and responsibilities for the following are established and documented:				
(1) record transmittal				
(2) record distribution				
(3) record retention				
(4) record maintenance				
(5) record disposition.				
C. Records are classified and maintained.				
(1) Lifetime Records (typical) are defined as				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(a) those which have significant value in demonstrating capability for safe operation (b) those which have significant value in maintaining, reworking, repairing, replacing, or modifying of a component or system (c) those which would have significant value in determining the cause of an accident or malfunction of a component or system (d) those which provide baseline data for studies establishing site characterization (e) those which reflect the as-built (i.e., analyzed, designed, fabricated, installed, and tested) condition of the repository. (2) Nonpermanent Records are defined as (a) those required to show evidence that an activity was performed in accordance with applicable requirements but not retained for the life of the item because they do not meet the criteria of lifetime records (b) Typical NPR's to be retained 10 years after superseded or invalidated include				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
1) QAPP's				
2) Technical procedures				
3) Audit and Survey reports				
4) Personnel qualifications				
5) QAP's				
6) Criteria letters				
7) Work orders				
8) Calibration records.				
D. Records Administration				
(1) Records system				
(a) A records system was established at earliest practical time.				
(b) The records system is defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(2) Generation of records (a) Records to be maintained by or for the Owner are identified in applicable design specifications, procurement documents, etc. (b) Documents designated to become records are legible, accurate, and completed appropriate to work accomplished. (3) Record validation (a) Documents considered valid records are stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. (b) Records are originals or reproduced copies. (4) Index (a) Records are indexed. (b) Indexing system includes, as minimum, the following: 1) record retention time 2) location of record within record system.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(5) Distribution (a) Records are distributed, handled, and controlled in accordance with written procedures. (6) Identification (a) Records and/or indexing system provides information to permit identification between the record and the item or activity to which it applies. (7) Corrected information in records (a) Records are corrected in accordance with written procedures which provide for review or approval by the originating organization. (b) Corrections include date and identification of the person authorized to issue the correction. E. Receipt (1) Individual or organization responsible for receiving records provides protection from damage or loss during time records are in their possession. (2) Each organization responsible for receipt of records has designated a person or organization responsible for receiving the records.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(3) The designee is responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage.				
(4) As a minimum, the receipt control system includes:				
(a) a method for designating required records				
(b) a method for identifying records received				
(c) procedures for receipt and inspection of incoming records				
(d) a structure to permit a current and accurate assessment of the status of records during the receiving process.				
F. Storage, preservation, and safekeeping				
(1) Storage				
(a) Records are stored in predetermined locations.				
(b) A written procedure is prepared and responsibility assigned for enforcing it.				
(c) The procedure includes as a minimum:				
1) a description of the storage facility				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
2) the filing system to be used 3) a method for verifying that the records received are in agreement with the transmittal document and that the records are legible 4) a method of verifying that the records are those designated 5) the rules governing access to and control of the files 6) a method for records removed from the storage facility 7) a method for filing supplemental information and disposing of superseded records. (2) Preservation (a) Records are stored in manner approved by organization responsible for storage. (b) To preclude deterioration of records, the following apply:				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
1) Provisions are made in the storage arrangement to prevent damage from moisture, temperature, and pressure. 2) Records are firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers. 3) Provisions are made for special processed records (such as radiographs, photographs, negatives, microfilm, and magnetic media) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity. (3) Safekeeping (a) Measures are established to preclude entry of unauthorized personnel in storage area. (b) Measures are established to guard against larceny and vandalism. (c) Measures provide controlled conditions for the prompt replacement, restoration, or substitution of lost or damaged records.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(4) Facility				
(a) Records are stored in facilities to minimize against damage or destruction from				
1) natural disasters such as winds, floods, or fires				
2) environmental conditions such as high and low temperatures and humidity				
3) infestation of insects or rodents.				
(b) Single Facility Criteria				
1) reinforced concrete, masonry, etc., construction				
2) floor and roof drainage control (check valve for floor drain)				
3) sealant over wells as moisture or condensation barrier				
4) minimum of 2-hour fire rating on door, frames, and hardware				
5) forced air circulation				
6) fire protection system.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(c) Alternate Single Facility Criteria 1) 2-hour fire rated vault meeting NFPA 232-1975 or 2) 2-hour fire rated Class B file containers meeting NFPA 232-1975 or 3) 2-hour fire rated file room meeting the requirements of NFPA 232-1975 with the following additional requirements a) early warning fire detection system b) record storage in metal cabinets c) 2-hour fire rated dampers or doors in all boundary penetrations. (d) Dual Facility Criteria 1) locations remote from each other to eliminate exposure to a simultaneous hazard 2) each facility to meet the other requirements of the checklist.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
G. Retrieval (1) Storage systems provide for retrieval of information in accordance with planned retrieval times based upon the record type. (2) A list is maintained designating those persons who have access to the files. (3) Records maintained by the supplier are accessible to the purchaser or his designated alternate. H. Disposition (1) Records accumulated at various locations are accessible to the Owner. (2) The record custodian inventories the submittals, acknowledges receipt, and processes records accumulated at various locations in accordance with the QA Program requirements. (3) Supplier's nonpermanent records are not disposed of until the applicable conditions listed below are satisfied: (a) purchaser's requirements are satisfied (b) regulatory requirements are satisfied				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(c) operational status permits				
(d) warranty consideration is satisfied.				
18. Audits				
A. Planned and scheduled audits are performed to verify compliance with all aspects of the QA program and to determine its effectiveness.				
B. Audits are performed in accordance with written procedures or checklists.				
C. Audits are performed by personnel who do not have responsibility for performing the activities being audited.				
D. Audit results are documented.				
E. Audit results are reported to and reviewed by responsible management.				
F. Audit follow up actions are taken where indicated.				
G. Scheduling				
(1) Internal or external QA audits, or both, are scheduled to provide coverage and coordination with ongoing QA Program activities.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(2) Audits are scheduled at a frequency commensurate with the status and importance of the activity.				
(3) Audit schedule is reviewed periodically and revised as necessary to assure coverage is maintained current.				
(4) Regularly scheduled audits are supplemented by additional audits of specific subjects necessary to provide adequate coverage.				
H. Preparation				
(1) Audit plan				
(a) An audit plan identifying the following is developed and documented for each audit:				
1) audit scope				
2) requirements				
3) audit personnel				
4) activities to be audited				
5) organization to be notified				
6) applicable documents				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
7) schedule				
8) written procedures or checklists.				
(2) Personnel				
(a) Auditors are independent of any direct responsibility for performance of activities which they will audit.				
(b) Personnel having direct responsibility for performing the activities being audited are not involved in selection of the audit team.				
(c) Audit personnel have sufficient authority and organizational freedom to make the audit process meaningful and effective.				
(3) Selection of Audit Team				
(a) Audit team is identified prior to beginning of each audit.				
(b) The audit team contains one or more auditors with one individual appointed to lead the team.				
(c) The individual appointed to lead:				
1) organizes and directs the audit				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
2) coordinates preparation and issuance of audit report 3) evaluates responses 4) ensures that the audit team is prepared prior to initiation of the audit. I. Performance (1) Audits are performed in accordance with written procedures or checklists. (2) Elements selected for audit are evaluated against specified requirements. (3) Objective evidence is examined to determine if selected elements are being implemented effectively. (4) Audit results are documented by auditing personnel. (5) Audit results are reviewed by management having responsibility for the area audited. (6) Conditions requiring prompt corrective action are reported immediately to management of the audited organization.				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
J. Reporting				
(1) The audit report is signed by the audit team leader and issued.				
(2) The audit report includes the following information as appropriate:				
(a) description of audit scope				
(b) identification of auditors				
(c) identification of persons contacted during audit				
(d) summary of audit results, including a statement on effectiveness of the QA Program elements audited				
(e) description of each reported adverse audit finding in sufficient detail to enable corrective action.				
K. Response				
(1) Management of audited organization or activity:				
(a) investigates adverse audit findings				

CHARACTERISTICS	REFERENCE DOCUMENT	RESULTS SAT.	RESULTS UNSAT.	OBJECTIVE EVIDENCE/REPORTS
(b) schedules corrective action, including measures to prevent recurrence (c) notifies appropriate organization in writing of action taken or planned. (2) The adequacy of audit responses are evaluated by or for the auditing organization. L. Follow up action is taken to verify whether corrective action is accomplished as scheduled. M. Records (1) Audit records include: (a) audit plans (b) audit reports (c) written replies (d) record of completion of corrective action.				