



South Texas Project Electric Generating Station P.O. Box 289 Wadsworth, Texas 77483

April 30, 2007
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10CFR50.54(a)
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U. S. Nuclear Regulatory Commission
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South Texas Project
Units 1 and 2
Docket Nos. STN 50-498 and STN 50-499
Submittal of Operations Quality Assurance Plan Change QA-065


The STP Nuclear Operating Company (STPNOC) submits the attached change to revision 17 of the Operations Quality Assurance Plan (OQAP). This change incorporates comments received from the Nuclear Regulatory Commission during a telephone call on April 19, 2007 in regards to submitted OQAP change QA-064. Clarifications were made to specifically indicate that use of commercial-grade calibration services is limited to accreditation by the National Voluntary Laboratory Accreditation Program (NVLAP) and American Association of Laboratory Accreditation (A2LA) which is recognized by NVLAP through the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement. The other clarification was to change the term Mutual Recognition Agreement to Mutual Recognition Arrangement.

This change is a clarification to previously submitted change QA-064 that mirrors a Safety Evaluation Report (SER) for Arizona Public Service Company's Palo Verde Nuclear Generating Station, Units 1, 2, and 3 (Reference TAC NOS. MC 4402, MC 4403, and MC 4404). This same interpretation is applicable to STPNOC. This change therefore does not represent a reduction in commitment and does not require Nuclear Regulatory Commission approval prior to implementation in accordance with the provisions of 10CFR50.54(a)(3)(ii).

Q004

There are no commitments in this letter.

If there are any questions regarding this matter, please contact Mr. T. F. Walker at (361) 972-7392 or me at (361) 972-8757.



J. J. Sheppard
President and Chief
Executive Officer

Attachment: 1. Operations Quality Assurance Plan change QA-065

cc:

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CHANGE QA-065
SUMMARY OF CHANGES
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ALL CHANGES ARE IN BOLD TYPE

CHAPTER	LOCATION	ACTION	TEXT
TOC	CH 2.0	INSERT	QA-065
TOC	CH 7.0	INSERT	QA-065
CH 2.0	Table I, ANSI N45.2.13, Full Program	DELETE	Section 3.2.3 – Nationally-recognized accrediting bodies include the National Voluntary Laboratory Accreditation Program (NVLAP) administered by the National Institute of Standards and Technology (NIST) and other accrediting bodies recognized by NVLAP via a Mutual Recognition Agreement (MRA)
CH 2.0	Table I, ANSI N45.2.13, Full Program	INSERT	Section 3.2.3 item 2) – the National Voluntary Laboratory Accreditation Program and () around NVLAP followed by administered by the National Institute of Standards and Technology (NIST) and Mutual Recognition Arrangement and () around MRA
CH 2.0	Table I, R.G. 1.144, Full Program	DELETE	Section C.3.b(2) – Nationally-recognized accrediting bodies include the NVLAP administered by the NIST and other accrediting bodies recognized by NVLAP via a MRA.
CH 7.0	5.2.2.1	DELETE	Nationally-recognized accrediting bodies include the National Voluntary Laboratory Accreditation Program (NVLAP) administered by the National Institute of Standards and Technology (NIST) and other accrediting bodies recognized by NVLAP via a Mutual Recognition Agreement (MRA).
CH 7.0	5.2.2.2	RENUMBER	5.2.2.1
CH 7.0	New 5.2.2.1, second bullet	INSERT	the National Voluntary Laboratory Accrediting Program and () around NVLAP and administered by National Institute of Standards and Technology (NIST) and Mutual Recognition Arrangement and ()

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ALL CHANGES ARE IN BOLD TYPE

CHAPTER	LOCATION	ACTION	TEXT
			around MRA
CH 7.0	5.6.3	DELETE	Nationally-recognized accrediting bodies include the NVLAP administered by the NIST and other accrediting bodies recognized by NVLAP via a MRA.

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	Definitions	9	2-1-02	
1.0	Organization	13	2-1-06	QA-060, 061, 062
2.0	Program Description	15	2-1-06	QA-060, 061, 064 065
3.0	Conduct of Plant Operations	7	2-1-98	
4.0	Qualification, Training, and Certification of Personnel	6	2-1-98	
5.0	Maintenance, Installation of Modifications, and Related Activities	5	2-1-98	
6.0	Design and Modification Control	9	2-1-06	
7.0	Procurement	10	2-1-06	QA-060, 061, 064 065
8.0	Control and Issuance of Documents	6	2-1-98	
9.0	Control of Material	6	2-1-98	
10.0	Inspection	10	2-1-06	QA-061
11.0	Test Control	7	2-1-00	QA-060, 061
12.0	Instrument and Calibration Control	6	2-1-98	
13.0	Control Of Conditions Adverse to Quality	11	2-1-06	QA-061
14.0	Records Control	8	2-1-06	
15.0	Quality Oversight	10	2-1-06	QA-060, 061, 063

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Activities

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16.0	Independent Technical Review	9	2-01-06	QA-060, 061
17.0	ASME Code Section XI - Repairs and Replacements	7	2-01-06	QA-060, 061, 062
18.0	ASME Code Section XI - Inservice Inspection and Testing	8	2-01-06	QA-061, 062
19.0	Administrative Controls	2	2-01-06	QA-060

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1.0 PURPOSE

1.1 The purpose of this chapter is to define criteria and establish administrative controls for implementation of the Quality Assurance (QA) Program for the South Texas Project Electric Generating Station (STP).

2.0 SCOPE

2.1 The QA Program is implemented and controlled in accordance with the Operations Quality Assurance Plan (OQAP) and is applicable to structures, systems, and components to an extent consistent with their importance to safety, and complies with the requirements of 10CFR50, Appendix B and other program commitments as appropriate.

2.2 The QA Program will also extend, as applicable and/or determined by STP management, to programs including 10CFR71, Subpart H (except design and fabrication of NRC certified radioactive waste shipping casks), ASME Boiler and Pressure Vessel Code, Sections III and XI; and to quality-related areas as defined herein including the Fire Protection Program, Emergency Plan, Radiological Environmental Monitoring Program, Radwaste Management Program, Computer Program Verification and Control, Seismic and Environmental Equipment Qualification Programs, Radiation Protection Program, and Station Blackout (SBO) systems and equipment.

2.3 The QA Program provides the basis for the control and performance of safety-related and quality-related activities associated with Early Site Permitting/COL Application activities for additional units (3 & 4) at the STPEGS. Controls, as currently stated in the OQAP, will be extended to specific activities associated with the new units by inserting an applicability statement in the Purpose and Scope of station procedures. These specific QA Program controls for the new units remain in effect until the Nuclear Regulatory Commission approves a Quality Program specific to the new units, and the associated implementing procedures are in place.

3.0 DEFINITIONS

3.1 Comprehensive Risk Management - A process by which the change in risk to station personnel, the public's health and safety are evaluated as a result of changes in commitments, processes, activities, and human and equipment performance.

QA-061

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- 3.2 Graded Quality Assurance - The process by which risk-based methodology [i.e., Probabilistic Safety Assessment (PSA)] and deterministic and performance-based information analyses are combined to establish appropriate levels of programmatic controls for SSCs and appropriate levels of first line and independent oversight needed to provide the necessary assurance that SSCs will operate safely.
- 3.3 Full program controls - The highest levels of controls and oversight applied to safety-related SSCs categorized as High Safety Significant (HSS), as prescribed in Table I to this chapter and throughout individual OQAP chapters.
- 3.4 Basic program controls - Levels of control and oversight, lower than in the Full Program, applied to safety-related SSCs categorized as Medium Safety Significant (MSS), as prescribed in Table I to this chapter and throughout individual OQAP chapters.
- 3.5 Targeted program controls - Selected program controls applied to certain non-safety-related SSCs categorized as either HSS or MSS.
- 3.6 Limited program controls - Limited controls applied to safety-related SSCs categorized as either Low Safety Significant (LSS) or Non-Risk Significant (NRS).
- 4.0 REFERENCES
- 4.1 10CFR50, Appendix B
- 4.2 10CFR71, Subpart H
- 4.3 ASME B&PV Code
- 4.4 OQAP Chapter 14.0, Records Control
- 4.5 10CFR50.63, Loss of All Alternating Current Power
- 4.6 10CFR50.54(a)
- 4.7 Updated Final Safety Analysis Report
- 4.8 Safety Evaluation on Exemption Requests from Special Treatment Requirements of 10 CFR Parts 21, 50, and 100 (TAC NOS. MA6057 AND MA6058)

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5.0 REQUIREMENTS

5.1 General Program Requirements

- 5.1.1 The OQAP shall be prepared and maintained to prescribe the STP QA Program. The OQAP reflects the quality program policies to be implemented. The OQAP describes the organization and responsibilities for attainment of quality objectives and verification of conformance to established requirements. The QA Program shall be in effect throughout the operating life of the STP.
- 5.1.2 The President and Chief Executive Officer has overall responsibility for quality assurance. The General Manager, Oversight is responsible for the development and maintenance of the OQAP for Units 1 & 2. The Vice President Oversight & Regulatory Affairs is responsible for the development and maintenance of the OQAP for Units 3 & 4.
- 5.1.3 The operations phase of the STP includes design, procurement, fabrication, repair, testing, operation, maintenance, refueling, inspection, independent oversight, modification, and other activities as discussed Table I to this chapter and throughout the OQAP. STP and its vendors are required, as appropriate, to comply with the criteria established by 10CFR50, Section 50.55a; 10CFR50, Appendix A, General Design Criterion (GDC) 1; 10CFR50, Appendix B, and 10CFR71, Sub-Part H (except design and fabrication of NRC certified radioactive waste shipping casks). These regulations are not applicable to LSS and NRS safety-related components, to the extent that the Nuclear Regulatory Commission has granted STP an exemption from the regulations as described in Reference 4.8.

STP will implement, as specified, the Regulatory Guides (RG) and implementing American National Standards Institute (ANSI) standards contained in Table I of this chapter.
- 5.1.4 STP shall maintain the OQAP as an effective and meaningful document to provide programmatic direction for the station. Changes to the OQAP shall be accomplished as prescribed by 10CFR50.54(a). When changes are made in the OQAP to the organizational elements only, appropriate notification will be made to the NRC within 30 days of implementation.

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5.2 Organizational Independence

5.2.1 The reporting arrangement utilized by the Quality organization ensures that those personnel performing independent oversight have the organizational freedom to:

5.2.1.1 Identify quality problems.

5.2.1.2 Initiate, recommend, or provide solutions.

5.2.1.3 Verify implementation of solutions.

5.2.2 Personnel verifying compliance with quality requirements do not have direct responsibility for the performance of or directly supervise the activity being verified.

5.3 Graded Quality Assurance

5.3.1 Graded Quality Assurance (GQA) is fundamental to the STP QA Program. It is described in more detail in the implementing procedure for the STP Comprehensive Risk Management (CRM) Program.

5.3.2 GQA is a process by which risk-based methodology [i.e., Probabilistic Safety Assessment (PSA)], deterministic insights, and performance-based information are combined and analyzed to determine what levels of programmatic controls are needed for structures, systems, and components (SSCs) and what levels of first line and independent oversight are needed to provide assurance that items will operate safely and activities are accomplished as prescribed.

5.3.3 Selected systems are evaluated, at the component level, by a cross-discipline Expert Panel comprised of high level station management. Initial evaluations are performed by the Working Group.

5.3.4 These recommendations are developed in consideration of the risk significance of system functions, components' contribution to core damage frequency and large early release frequency, components' critical attributes (needed to support risk significant system functions), performance, regulatory/QA requirements, and other deterministic considerations as prescribed in the Comprehensive Risk Management procedures.

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- 5.3.5 Program control recommendations are developed by the Working Group and ultimately approved by the Expert Panel and forwarded to the site for implementation. Controls are implemented in four graded applications (i.e., “Full”, “Basic”, “Targeted”, and “Limited”).
- 5.3.6 “Full” program controls are applied to safety-related SSCs categorized as HSS. These “Full” levels of controls and oversight are designed to provide a high degree of confidence that SSCs perform safely and activities are performed as expected. Table I to the OQAP chapter prescribes the program commitments applicable to “Full” program activities.
- 5.3.7 "Basic" program controls are applied to safety- related SSCs categorized as MSS. These are lower levels of control and oversight, designed to maintain/preserve those identified critical attributes of SSCs needed to support risk significant system functions. These controls are intended to reflect economical and efficient business practices. Table I to the OQAP chapter prescribes the program commitments applicable to "Basic" program activities.
- 5.3.8 “Limited” program controls are applied to safety-related SSCs categorized as either LSS or NRS. Only specific program controls related to the activities listed in the following subparagraphs are applicable to these SSCs. The other chapters of the OQAP are not applicable to safety-related LSS and NRS SSCs. Instead, the treatment processes applicable to these SSCs are described in the Updated Final Safety Analysis Report Section 13.7.3.3 and implementing procedures:
- 5.3.8.1 Those elements in Chapter 1.0 that are needed to implement and control activities described above;
 - 5.3.8.2 Applicable requirements in this Chapter;
 - 5.3.8.3 Modification/design activities as described in Chapter 6.0; and
 - 5.3.8.4 Corrective action as described in Chapter 13.0.
- 5.3.9 “Targeted” program controls are applied to non-safety related SSCs, for which 10CFR50, Appendix B is not applicable, categorized as HSS or MSS . Specific program controls consistent with applicable portions of the "full" and "basic" program controls are applied to those items in a selected manner, "targeted" at those characteristics or critical attributes that render the SSC risk significant.

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5.3.10 Safety-related components that are highly reliable, yet whose failure would result in a significant increase in risk, will receive Full program coverage, or will be evaluated based on their risk significance to ensure that Full program controls are applied to their critical attributes.

5.3.11 SSCs governed by the OQAP shall retain their current program coverage until such time as prescribed risk-informed, performance-based analyses are completed and approved, and they are placed into the graded program categories (i.e., "Full", "Basic", "Targeted", or "Limited") as appropriate.

5.3.12 A vital element of the GQA program is the "feedback" loop. On a periodic basis, and as prescribed in the Comprehensive Risk Management procedure, the GQA Working Group and Expert Panel shall review any changes to the PSA information and performance/operating experience that could result in recategorization of an SSC. These reviews are also used to assess the effectiveness and appropriateness of in-place quality program controls. Adjustments shall be made as determined necessary.

5.4 Delegation of QA Functions

5.4.1 The OQAP may be executed in whole or part by subcontract personnel. However, STP will retain responsibility for the total quality assurance program, and Quality organization personnel will perform appropriate oversight activities of subcontracted activities.

5.5 Identification of Safety Significant Structures, Systems, and Components

5.5.1 The program described herein is applied to activities affecting the safety functions of those structures, systems, and components which prevent, or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. The structures, systems, and components controlled are listed in UFSAR Section 3.2, along with their associated fire protection systems. UFSAR Section 3.2 also identifies those structures, systems, and components which may not represent a safety significant/risk important concern but to which the STP OQAP is applied.

5.5.2 The fire protection QA Program is part of the overall STP Operations QA Program. Fire protection QA Program criteria are implemented as part of the Operations QA Program.

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5.5.3 Expendable or consumable items necessary for the functional performance of structures, systems, and components are subjected to quality assurance requirements as specified in written procedures. These procedures include provisions for review and control in accordance with industry standards and specifications.

5.6 QA Program Documents

5.6.1 The QA Program shall be implemented with documented instructions, procedures, and drawings which include appropriate quantitative and qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. Procedures shall include the control of the sequence of required inspections, tests, and other operations when important to quality. To change these controls, the individual procedure must be changed and shall require the same level of review and approval given to the original procedure. Such instructions, procedures, and drawings are reviewed and approved for compliance with requirements appropriate to their safety significance by individuals qualified to do so.

5.7 Personnel Indoctrination and Training

5.7.1 General indoctrination and training programs shall be provided for site personnel to assure that they are knowledgeable regarding quality programs and requirements. The training requirements for STP personnel are described in UFSAR Section 13.2. Personnel performing complex, unusual, or potentially hazardous work shall be instructed in special indoctrination or briefing sessions. Emphasis shall be on special requirements for safety of personnel, radiation control and protection, unique features of equipment and systems, operating constraints, and control requirements in effect during performance of work. Where required by codes and standards, personnel are trained, qualified, and certified according to written procedures in the principles and techniques of performing specific activities.

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5.8 Policies and Goals

5.8.1 STP policy is to assure that the design, procurement, construction, testing, and operation of the STP are in conformance with specifications, procedures, codes, commitments and Nuclear Regulatory Commission (NRC) regulations to the extent not exempted. The responsibility of each organization supporting the STP is to ensure that the requirements stated in this QA Program are incorporated into procedures. Adherence to those procedures is mandatory for all STP organizations and contractors or vendors providing items or services covered by the QA Program.

5.8.2 The OQAP identifies activities and establishes requirements for procedures which identify, report, and verify the resolution of quality problems. The implementing procedures call for the resolution of quality problems at the lowest possible authorized level. However, if a dispute is encountered in the resolution of a quality problem which cannot be resolved at lower levels, the General Manager, Oversight or Manager, Quality shall present the problem to the President and Chief Executive Officer for resolution. The Group Vice President or the Vice President Oversight & Regulatory Affairs shall present the problem to the President and Chief Executive Officer for Units 3 & 4.

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5.9 Control of Activities

5.9.1 The OQAP requires Quality department review and/or approval of procedures which control selected activities. These procedures shall require the use of the proper equipment, completion of prerequisites for starting an activity, and suitable environment for performing the activity. Procedures will comply with the appropriate standards.

5.9.2 STP personnel attend planning, scheduling, and status meetings as necessary to assure adequate quality coverage and program application exists.

5.10 Management Review

5.10.1 The implementation of both line and OQAP requirements shall be verified through independent oversight activities. The Quality organization shall conduct independent oversight activities of the operating plant and of the interfacing organizations' activities.

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5.10.2 Independent oversight of the implementation of the OQAP is conducted under the cognizance of the Senior Management Team and results are transmitted to appropriate line and senior management, including the President and Chief Executive Officer for review and/or action.

5.10.3 STP may use the services of architect-engineer firms, Nuclear Steam Supply System (NSSS) suppliers, fuel fabricators, constructors, and others which provide or augment STP efforts during operations. As applicable, the QA programs of such contractors or consultants shall be subject to review, evaluation, and acceptance by the Quality organization before initiation of activities affected by the program.

5.11 Computer Code Programs

5.11.1 The development, maintenance, and use of computer code programs will be controlled. Prior to use of a computer code program, the appropriateness of the program shall be verified. In addition, all such programs shall be appropriately certified for use.

6.0 DOCUMENTATION

6.1 Procedures which are generated as required by this chapter shall identify the records which are required to implement and document those activities. The records shall be controlled in accordance with Reference 4.4.

7.0 ATTACHMENTS

7.1 Table I - Program Commitments

TABLE I
PROGRAM COMMITMENTS

R.G./ANSI STANDARD	FULL PROGRAM	BASIC PROGRAM
R.G. 1.8, rev. 1 (9/75)	No exceptions taken.	No exceptions taken.
ANSI N18.1, 1971	4.2.2-The Operations Manager requirements regarding holding a Senior Reactor Operator license are met by the Unit Operations Managers.	Same as full.
R.G. 1.28, rev. 0 (6/72)	This R.G. is not applicable to operations phase activities.	Same as full.
ANSI 45.2, 1971	This standard is not applicable to operations phase activities.	Same as full.
R.G. 1.33, rev. 2 (2/78)	<p>C.2 - the specific revisions of the listed standards to which STP is committed are in this table and are not necessarily the "latest" revision.</p> <p>C.4 – Chapter 15.0 of the STP OQAP describes the audit program at STP that meets the intent of R.G. 1.33, rev. 2, position C.4 regarding frequency of audits</p> <p>C.4.a.b.c – STP performs these audits in accordance with a nominal biennial frequency.</p>	<p>Same as full.</p> <p>Same as full.</p> <p>Same as full.</p>
ANSI N18.7 – 1976/ANS 3.2	<p>3.4.2 – refer to R.G. 1.8 regarding Operations Manager holding a Senior Reactor Operator license.</p> <p>4.5 – refer to R.G. 1.33 coverage regarding audit frequency.</p> <p>5.2.6 (5th paragraph) – independent verification may be concurrent with (same time as) work performance.</p>	<p>Same as full.</p> <p>3.4.2 refer to R.G. 1.58 regarding use of personnel not qualified in accordance with ANSI N45.2.6.</p> <p>Same as full.</p> <p>Same as full.</p>

TABLE I
PROGRAM COMMITMENTS

R.G./ANSI STANDARD	FULL PROGRAM	BASIC PROGRAM
ANSI N18.7/ANS 3.2 (cont'd)	<p>5.2.7 (1st paragraph) – STP will use current approved design bases as opposed to original design bases.</p> <p>5.2.7.1 (5th paragraph) – STP takes exception to use of the word “promptly” with regard to determining, evaluating and recording the causes of malfunctions. The STP Corrective Action Program includes the elements with regard to timeliness of action associated with causal analyses.</p> <p>5.2.15 (4th paragraph) – Chapter 8.0 of the OQAP describes the requirements for control and issuance of documents, which meets the intent of R.G. 1.33, rev. 2. The intent of the biennial review is accomplished by other controls that assure that procedures are appropriately reviewed and revised to incorporate information based on plant operations, design changes, regulatory requirements, industry experience and other conditions that may impact plant procedures.</p>	<p>Same as full.</p> <p>5.2.7 – STP will perform inspection as deemed necessary, based on the relative complexity of the work.</p> <p>Same as full.</p> <p>5.2.7.2 – refer to table coverage of ANSI N45.2.11, 1974.</p> <p>5.2.13 (1st paragraph) – refer to table coverage of ANSI N45.2.13, 1976.</p> <p>5.2.13.1 (1st paragraph) – refer to table coverage of ANSI N45.2, 1971.</p> <p>5.2.13.4 (5th paragraph) – refer to table coverage of ANSI N45.2.2, 1972.</p> <p>Same as full.</p>

TABLE I
PROGRAM COMMITMENTS

R.G./ANSI STANDARD	FULL PROGRAM	BASIC PROGRAM
ANSI N18.7/ANS 3.2 (cont'd)		5.2.17 (3rd paragraph) – STP may not implement the requirement for conduct of inspections in a manner similar to that associated with construction phase activities (i.e., regarding use of personnel not qualified to ANSI N45.2.6)
R.G. 1.38, rev. 2 (5/77)	No exceptions taken.	No exceptions taken.
ANSI N45.2.2, 1972	2.4 – Audit personnel are qualified in accordance with STP's commitment to R.G. 1.146/ANSI 45.2.23.	Same as full.
		2.4 – Offsite oversight of vendors of items in the Basic category will only be performed as deemed necessary.
	5.2.1 - These activities do not constitute an "inspection" as defined in ANSI/ASME NQA-1, 1983, Supplement S-1, Terms and Definitions. Therefore, the requirements for qualification to ANSI N45.2.6 as stated in Section 2.4 do not apply to personnel performing these activities.	Same as Full
R.G. 1.58, rev. 1 (9/80)	C.2 – STP is committed to ASNT-TC-1A, 1980. STP treats the recommendation (“should”) of the 1980 edition as requirements (“shall”).	Same as full.
ANSI N45.2.6, 1978.		1.2 (1st paragraph) – with the exception of receipt inspection, personnel may perform inspections, examinations and tests provided they are experienced, task qualified journeymen, or supervisors, who did not perform or directly supervised the activity being inspected, examined or

TABLE I
PROGRAM COMMITMENTS

R.G./ANSI STANDARD	FULL PROGRAM	BASIC PROGRAM
ANSI N45.2.6, 1978 (cont'd)		tested. These individuals shall also receive training to the applicable inspection procedure, processes, methods in accordance with a Quality approved training program; and Quality will provide periodic oversight of the inspection activities.
	1.2 (3rd paragraph) – refer to table coverage of R.G. 1.28.	Same as full.
	1.4.4 – refer to table coverage of R.G. 1.74/ANSI N45.2.10.	Same as full.
	Personnel performing the activities stated in ANSI N45.2.2, Section 5.2.1 do not require qualification to this Standard. (see exception to ANSI N45.2.2)	Same as Full
R.G. 1.64, rev. 2 (6/76)	No exceptions taken.	C.2 – STP may implement the requirement regarding design verification as prescribed in ANSI N45.2.11, 1974, 6.1, second paragraph/second sentence, as opposed to R.G. wording.
ASNI N45.2.11, 1974	No exceptions taken.	3.2 (1 st paragraph) – STP will require personnel to consider items 1 through 28, but a documented checklist may not be required.

TABLE I
PROGRAM COMMITMENTS

R.G./ANSI STANDARD	FULL PROGRAM	BASIC PROGRAM
ANSI N45.2.11, 1974 (Con't.)		6.3 – Verification and checking of design may be accomplished through supervisory or management review/approval as provided for in 6.1. Personnel will be required to consider items 1 through 19, but a documented checklist may not be required.
R.G. 1.74 (2/74)	Not applicable to STP. STP uses ANSI/ASME NQA-1-1983 for Quality Assurance Terms and Definitions.	Same as full.
ANSI N45.2.10, 1973	Same as R.G. 1.74 above.	Same as full.
R.G. 1.88, rev. 2 (10/76)	No exceptions taken.	Same as full.
ANSI N45.2.9, 1974	Section 5.6 – supplement the provisions of this section by providing for alternate temporary storage of records. Allow the use of 1-hour fire rated cabinets to store records that are awaiting processing (e.g., processing into Optical Disk Storage). Storage of these records in 1-hour fire rated cabinets will be controlled by procedure which specify a maximum allowable time limit. Cabinets housing these records shall be controlled for access and shall be located in an area protected by sprinklers.	Same as full.
R.G. 1.123, rev. 1 (7/77)	C.6.b.and e. – The referenced section of ANSI N45.2.13 will be implemented as written.	
ANSI N45.2.13, 1976	Various sections refer to ANSI N45.2. Refer to table coverage of R.G. 1.28 and ANSI N45.2.	Same as full.

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R.G./ANSI STANDARD	FULL PROGRAM	BASIC PROGRAM
ANSI N45.2.13, 1976 (cont'd)	<p>3.2.3 – When purchasing commercial-grade calibration services from calibration laboratories accredited by a nationally-recognized accrediting body, the procurement documents are not required to impose a quality assurance program consistent with 10CFR50, Appendix B. In such cases, accreditation may be accepted in lieu of the Purchaser imposing a QA Program consistent with 10CFR50, Appendix B, provided all of the following are met:</p> <ol style="list-style-type: none"> 1) The accreditation is to ANSI/ISO/IEC 17025 2) The accrediting body is either the National Voluntary Laboratory Accrediting Program (NVLAP) administered by the National Institute of Standards and Technology (NIST) or American Association for Laboratory Accreditation (A2LA). The A2LA accreditation is recognized by NVLAP through the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA). 3) The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties. This requires the supplier to provide a measurement of collective uncertainty and obviates the need to impose the four-to-one ratio requirement discussed in NIST Information Report (NISTIR) 6989. 4) The purchase documents impose additional technical and administrative requirements, as necessary, to satisfy STPNOC QA Program and technical requirements. This requires the calibration certificate/report include identification of the laboratory equipment/standards used. 5) Purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance. 	Same as full
	5.3 and 5.4 – Provision are established for, in special cases and with management approval, completion of these activities after award of contract.	Same as full.
	9.0 – This section will be implemented based on the scope, complexity and safety significance of the items being procured.	Same as full.

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R.G./ANSI STANDARD	FULL PROGRAM	BASIC PROGRAM
ANSI N45.2.13, 1976 (cont'd)		10.3.1 – This section will only be implemented as deemed necessary.
		12 – This section will only be implemented as deemed necessary for audits of suppliers.
R.G. 1.144, rev. 1 (9/80)	C.1 – refer to table coverage of R.G. 1.28 and ANSI N45.2.	Same as full.
	C.3a(1) – refer to table coverage of R.G. 1.33 regarding audit frequency.	Same as full.
	<p>C.3.b(2) – When purchasing commercial-grade calibration services from calibration laboratories accredited by a nationally-recognized accrediting body, the accreditation process and accrediting body may be credited with carrying out a portion of the Purchaser’s duties of verifying acceptability and effective implementation of the calibration service supplier’s quality assurance program.</p> <p>In lieu of performing an audit, accepting an audit by another licensee, or performing a commercial-grade survey, a documented review of the supplier’s accreditation shall be performed by the Purchaser. This review shall include, at a minimum, verification of the following:</p> <ol style="list-style-type: none"> 1) The accreditation is to ANSI/ISO/IEC 17025 2) The accrediting body is either NVLAP or A2LA. The A2LA accreditation is recognized by NVLAP through the ILAC MRA. 3) The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties. This requires the supplier to provide a measurement of collective uncertainty and obviates the need to impose the four-to-one ratio requirements discussed in NISTIR 6989. <p>The licensee is responsible for ensuring that the procured services are within the accredited scope of the NVLAP and A2LA certificates.</p>	<p>Same as full for commercial-grade calibration services</p> <p>STP will audit vendors only as deemed necessary. STP will perform biennial evaluations.</p>

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R.G./ANSI STANDARD	FULL PROGRAM	BASIC PROGRAM
ANSI N45.2.12, 1977	No exceptions taken.	STP will audit vendors only as deemed necessary. These audits will be conducted as unplanned/unscheduled audits.
R.G. 1.146, rev. 0 (8/80)	C.1 – refer to table coverage of R.G. 1.28 and ANSI N45.2. Refer to table coverage of R.G. 1.74 and ANSI N45.2.10	Same as full.
ANSI N45.2.23, 1978	1.2 – refer to table coverage of R.G. 1.28.	Same as full.
	1.4 – refer to table coverage of R.G. 1.74.	Same as full.
	2.21 – refer to table coverage of R.G. 1.28.	Same as full.
	2.3.3.1 – refer to table coverage of R.G 1.28.	Same as full.
	<p>2.3.4 - In lieu of the requirements of section 2.3.4 of ANSI N45.2.23-1978 the following alternative is acceptable:</p> <p>Prospective lead auditors shall demonstrate their ability to properly implement the audit process and effectively lead an audit team. This demonstration process will be described in implementing procedures and will include the evaluation and documentation of the results of the demonstration. Regardless of the methods used for the demonstration, the prospective lead auditor is required to participate in at least one nuclear quality assurance audit within the year preceding the individual's effective date of qualification. Upon successful demonstration of the ability to effectively implement the audit process and effectively lead audits, and having met the other provisions of Section 2.3 of ANSI N45.2.23-1978, the individual may be certified as being qualified to lead audits.</p>	Same as full

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For Regulatory Guides addressed by the table, and unless specific clarification or exception is indicated, STP will implement the Regulatory Guide positions, including recommendations.

For ANSI Standards addressed by this table, and unless specific clarification or exception is indicated, STP will treat ANSI requirements (i.e., “shall”) as such – except in instances where the standard itself provides options or requires a graded approach – this notwithstanding the general applicability statements found in many standards (i.e., section 1.0)

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1.0 PURPOSE

1.1 The purpose of this chapter is to establish the requirements for procurement of items and services for the South Texas Project Electric Generating Station (STP).

2.0 SCOPE

2.1 This chapter applies to the procurement of items and services for use at STP which are subject to the controls of this Quality program. These activities include procurement document control, bid evaluation, vendor evaluation, verification of vendor activities and receiving inspection.

3.0 DEFINITIONS

3.1 None

4.0 REFERENCES

- 4.1 10CFR50, Appendix B
- 4.2 10CFR21, Reporting of Defects and Noncompliance
- 4.3 OQAP Chapter 2.0, Table I
- 4.4 EPRI NP-5652 (NCIG-07), Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Application
- 4.5 OQAP Chapter 4.0, Qualification, Training and Certification of Personnel
- 4.6 OQAP Chapter 13.0, Control of Conditions Adverse to Quality
- 4.7 OQAP Chapter 14.0, Records Control
- 4.8 Generic Letter 89-02, Actions to Improve the Detection of Counterfeit and Fraudulent Marketed Products

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5.0 REQUIREMENTS

5.1 Procurement Document Preparation, Review and Control

5.1.1 Responsibility for procurement is a joint effort of all the departments within the STP Nuclear Operating Company (STPNOC). The department requesting the material or service provides technical content and quality requirements. Engineering/Supply Chain is responsible to provide input to the requesting department on technical content and quality requirements, as requested. Quality will concur with all changes to quality requirements.

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5.1.2 The sequence of preparation, review, approval, and issuance of procurement documents is generally as follows:

5.1.2.1 Purchase Requisitions

- Purchase requisition forms shall be used to initiate the procurement of materials, parts, components, and services. Procurement may be initiated by any STPNOC personnel.
- Purchase requisitions shall include material and component identification requirements, drawings, specifications, standards, inspection and test requirements, and special process instructions as appropriate.
- Purchase requisitions for materials, parts, components, or services shall be reviewed by the cognizant technical organization to verify that adequate technical and quality requirements have been specified.
- The reviews for technical and quality requirements shall be performed by someone other than the originator of the requisition. Quality will concur with all changes to quality requirements.

5.1.2.2 Purchase Orders and Contracts

- Purchase orders and contracts are prepared and issued by Supply Chain and establish for the suppliers the technical and quality requirements which must be met.

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- Purchase orders and contracts shall accurately reflect the technical and quality requirements established by the purchase requisition. If, during the bid negotiations with the supplier, it becomes necessary or commercially desirable to change the technical or quality requirements, such changes shall be presented for approval to the cognizant technical organization which approved the original requirements.

5.1.2.3 Change Controls

- Changes to procurement document quality and technical requirements shall require a review and approval equivalent to that of the original document. Commercial consideration changes not affecting the technical or quality requirements do not require review and concurrence by the originator.

5.1.3 For the procurement of spare or replacement parts, equipment, materials, and services, the quality and technical requirements shall be equal to or greater than the design basis requirements for the original part, equipment, materials or services; except where less stringent quality or technical requirements may be established based on specific evaluations and justification. The cognizant technical organization shall document such justification.

5.1.3.1 Items may be procured as Commercial Grade Items (CGIs) if a documented engineering evaluation indicates the CGI will provide equivalent performance. CGI dedication will comply with established procedures designed to satisfy the requirements of References 4.2 and 4.8.

5.1.3.2 The cognizant technical organization shall verify that quality requirements are correctly stated, verifiable, and controllable; that acceptance/rejection criteria are included; and that the documents have been prepared, reviewed, and approved in accordance with STP Quality Program requirements.

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5.2 Procurement Document Content

5.2.1 Procurement document control measures shall assure that appropriate regulatory requirements, design bases, and other requirements are included in the procurement process. The following shall be included or invoked by reference in procurement documents as appropriate:

- 5.2.1.1 Applicable regulatory, code, and design requirements, including material and component identification requirements, drawings, specifications, standards, inspection and test requirements, special process instructions and handling, preservation, cleaning, storage, packaging and shipping requirements. These requirements shall equal or exceed the original requirements (unless changed by established design control processes).
- 5.2.1.2 Extent that supplier QA program shall comply with 10CFR50, Appendix B or the QA program requirements of other nationally recognized codes and standards, as applicable; or for CGIs to be dedicated for safety related use by STPNOC based on the results of a survey of the vendor's controls, the vendor's STPNOC approved and/or surveyed program.
- 5.2.1.3 Requirements for supplier documents, such as instructions, procedures, drawings, specifications, inspection and test records, and suppliers' QA records to be prepared, submitted, or be made available for review and/or approval by STP personnel.
- 5.2.1.4 Requirements for suppliers to maintain the status of required inspections or tests throughout the manufacturing process to preclude inadvertent bypassing of inspections and tests.
- 5.2.1.5 Requirements for STPNOC's right of access to suppliers' facilities and work documents for inspection and audit.
- 5.2.1.6 Requirements for extending applicable STP procurement requirements to lower-tier suppliers and subcontractors, including STPNOC's access to facilities and records.
- 5.2.1.7 Requirements for supplier reporting to STP nonconformances to procurement document requirements and conditions for their disposition.

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5.2.1.8 Requirements for the retention, control, and maintenance of supplier QA records that are not maintained by STPNOC. Supplier-furnished records shall include:

- Documentation (e.g., certification) that identifies the purchased item and the specific procurement requirements (e.g., codes, standards, and specifications) met by the item.
- Documentation identifying any procurement requirements that have not been met.
- A description of those nonconformances from procurement requirements dispositioned "accept-as-is" or "repair".

5.2.1.9 Requirement for the supplier to submit a copy of its QA program description (does not apply for CGIs).

5.2.1.10 Requirements for the performance of maintenance and receipt inspection checks where applicable.

5.2.1.11 Applicability of 10CFR21 reporting requirements.

- The reporting requirements of 10CFR21 do not apply to vendors of CGIs to be dedicated for use by STPNOC.
- The reporting requirements of 10CFR21 do not apply to suppliers of commercial-grade calibration services.

5.2.2 When purchasing commercial-grade calibration services from calibration laboratories accredited by a nationally-recognized accrediting body, the procurement documents are not required to impose a quality assurance program consistent with 10CFR50, Appendix B.

5.2.2.1 In such cases, accreditation may be accepted in lieu of imposing a QA Program consistent with 10CFR50, Appendix B, provided all of the following are met:

- The accreditation is to ANSI/ISO/IEC 17025

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- The accreditation body is either the National Voluntary Laboratory Accrediting Program (NVLAP) administered by National Institute of Standards and Technology (NIST) or American Association for Laboratory Accreditation (A2LA). The A2LA accreditation is recognized by NVLAP through the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).
- The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties. This requires the supplier to provide a measurement of collective uncertainty and obviates the need to impose the four-to-one ratio requirement discussed in NIST Information Report (NISTIR) 6989.
- The purchase documents impose additional technical and administrative requirements, as necessary, to satisfy STPNOC QA Program and technical requirements. This requires the calibration certificate/report include identification of the laboratory equipment/standards used.
- Purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.

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5.3 Bid Evaluation

5.3.1 Bid Evaluations shall be performed to evaluate adherence to technical and quality assurance requirements.

5.4 Supplier Selection

5.4.1 Suppliers of items (for CGIs, when basis for dedication includes commercial grade survey) or services shall be required to submit copies of their QA program description for evaluation prior to the issuance of a purchase order or execution of a contract, and acceptability shall be documented. The process by which suppliers are judged as being a capable procurement source is described as follows:

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5.4.1.1 Procurement source evaluation and selection involves Engineering, Quality, Supply Chain, and STP plant personnel, as appropriate. These organizations participate in the qualification evaluation of suppliers in accordance with written procedures.

5.4.1.2 Measures for the evaluation and selection of procurement sources shall be specified in procedures and may vary depending upon the complexity and risk significance of the item or service. When procurement source evaluations are performed, the information to be considered shall include one or more of the following:

- Experience of users of identical or similar products of the prospective supplier, other utility or approved contractor audits/evaluations, audits/evaluations by cooperative utility groups, American Society of Mechanical Engineers (ASME) Certificates of Authorization, STP records accumulated in previous procurement actions, and STP product operating experience may be used in this evaluation. When other utility, contractor or cooperative utility audits/evaluations are used, the documentation will be obtained and reviewed. Supplier history shall reflect recent capability. Previous favorable experience with suppliers may be an adequate basis for judgments attesting to suppliers' capability.
- An evaluation of the suppliers' current quality records supported by documented qualitative and quantitative information which can be objectively evaluated. This may include review and evaluation of the suppliers' QA Program Manual, procedures, and responses to questionnaires, as appropriate.
- A source evaluation of the suppliers' technical and quality capability as determined by a direct evaluation of facilities and personnel (audit, survey, or surveillance) and quality program implementation. Resolution or a commitment to resolve unacceptable technical or quality requirements identified by the bid evaluation or vendor evaluation shall be obtained prior to the award of a purchase order or contract.

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- 5.4.1.3 Procurement source evaluations involve a review of technical and quality considerations to an extent considered appropriate by each participant. Technical considerations include the design or manufacturing capability and technical ability of suppliers to produce or provide the design, service, item or component. Quality considerations include one of the previously stated methods of supplier evaluation and a consideration of a suppliers' current quality program or capabilities.
- 5.4.1.4 A documented quality assurance evaluation of a vendor's quality program shall be performed to assure it meets the appropriate requirements of 10CFR50 Appendix B, or where applicable, other nationally recognized codes and standards, or, for CGIs, to assure the program provides adequate control over established critical characteristics.
- 5.4.1.5 Vendors may be placed on the Approved Vendors List after passing this evaluation.
- 5.4.1.6 A vendor shall not be issued a purchase order or contract unless they have been accepted for placement on the Approved Vendors List or an exception has been approved by the General Manager, Oversight or Quality Manager. Exceptions for Units 3 & 4 are approved by the Vice President Oversight & Regulatory Affairs.
- 5.4.1.7 Service organizations which will supply only manpower and no other service are not required to be on the Approved Vendors List or have an STP approved quality assurance program as long as the supplied personnel are trained and work under the auspices of the STP Operations Quality Assurance Plan.
- 5.4.2 Each vendor on the Approved Vendors List shall be periodically evaluated by Quality as provided by Reference 4.3 (i.e., annually for "Full" program, biennially for "Basic" program).
 - 5.4.2.1 A vendor may be removed from the Approved Vendors List if evaluation determines the vendor is unacceptable, the vendor requests removal or by direction of the General Manager, Oversight or Quality Manager or by direction of the Vice President Oversight & Regulatory Affairs for Units 3 & 4.

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5.4.3 Planning of verification activities to be employed for item or service acceptance shall begin during the purchase requisition or contract preparation and review stage. The extent of the verification activities will vary and be a function of the relative safety significance, complexity of the purchased item or service, and the supplier's past performance. The verification activities may include vendor surveillance, receipt inspection, or post-installation testing. Verification activities are planned to assure conformance to procurement document requirements. Procedures shall establish the organizational responsibilities for identifying required verifications and methods, performing and documenting the verification activities.

5.4.3.1 Verification activities shall be performed using plans developed in accordance with procedures with appropriate input from the cognizant technical organization. The plan shall specify the characteristics or processes to be witnessed, inspected or verified.

5.4.3.2 Specified source inspections may be waived by General Manager, Oversight or Quality Manager or by the Vice President Oversight & Regulatory Affairs for Units 3 & 4.

5.4.3.3 Vendor related reports shall be evaluated to determine the effectiveness of the vendor's quality assurance program.

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5.5 Receiving Activities

5.5.1 Received purchased items shall be observed for shipping damage and the requirements of ANSI N45.2.2 Section 5.2.1. (This activity does not constitute an inspection and does not require qualification in accordance with Reference 4.5).

5.5.2 Receiving inspection shall be coordinated with verification activities. If source inspection is not performed or did not address all applicable attributes, receipt inspection shall be performed and shall include the applicable additional attributes listed in ANSI N45.2.2 Section 5.2.2, except for commercial grade items dedicated by survey which shall be receipt inspected as required by the procurement document.

5.5.3 Receiving inspection checklists shall be developed using the requirements specified in the procurement documents and applicable attributes of ANSI N45.2.2.

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- 5.5.4 Statistical sampling methods may be used for groups of similar items. Sampling shall comply with nationally recognized methods or approved engineering alternates.
- 5.5.5 Receiving inspections shall be performed by personnel trained and qualified in accordance with Reference 4.5. Technical assistance shall be provided by Supply Chain or Engineering as applicable.
- 5.5.6 Receiving inspection activities shall include:
 - 5.5.6.1 Identifying materials, parts, and components and their status upon receipt by tagging or other acceptable means of identification, or segregating and controlling items in receiving hold areas separate from the storage facilities for acceptable items. Identification of items shall correspond to the identification required by procurement documents and be noted on receiving documentation.
 - 5.5.6.2 Verification of items for acceptance includes correctness of identification and specified quality documentation.
 - 5.5.6.3 Inspecting or testing using approved procedures and calibrated tools, gauges, and measuring equipment for verification acceptance of items, including off-the-shelf items.
 - 5.5.6.4 Items determined to be acceptable for use shall be identified with an "accept" tag or other acceptable means of identification prior to release for storage or use.
 - 5.5.6.5 Received items which do not conform to procurement documents are controlled and segregated (if practical) and processed in accordance with Reference 4.6.
- 5.5.7 Acceptance by post-installation test may be utilized following one of the preceding verification methods. Post-installation testing may be used for acceptance verification when it is difficult to verify item quality characteristics, the item requires an integrated system checkout or test, or the item cannot demonstrate its ability to perform when not in use. Engineering specifications shall be used for developing post-installation test instruction requirements and acceptance documentation. Post-installation testing is the responsibility of the Plant General Manager and is witnessed by Engineering or Quality personnel at specified hold points.

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5.5.8 Acceptance of Procured Items and Services

5.5.8.1 Acceptance of items and services shall be based on one or more of the following:

Written certifications

(Note: This shall not be the sole method of acceptance for items in the "Basic" program)

Surveillance/Audit of procured service

Source verification

Receiving inspection/testing

Commercial Grade Item dedication

Vendor surveillance

Post-installation test

5.5.9 Documented evidence from the supplier that procured items meet procurement quality requirements, when required, such as codes, standards, or specifications will be maintained at the plant site. Such evidence shall be provided by the supplier, at the time of source or receipt inspection, for review and verification before acceptance. The documented evidence will be retrievable and available at the plant site prior to installation or use of the procured item, unless otherwise controlled in accordance with Reference 4.6.

5.6 Vendor Surveys, Surveillance and Audit

5.6.1 For items in the Full Program, Suppliers Certificates of Conformance, shall be periodically evaluated by audits, independent inspections, surveys, or tests to assure that they are valid and results are documented. When acceptance is based upon source inspection, documented evidence shall be furnished to the plant receiving organization.

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5.6.1.1 Acceptance by source inspection may be considered when the item or service is vital to plant safety; or the quality characteristics are difficult to verify after receipt; or the item or service is complex in design, manufacture, inspection, or test. Vendor surveillance/source inspection involves a physical presence to monitor, by observation, designated activities for the purpose of evaluating supplier performance and product acceptance (source inspection only).

5.6.2 The STP survey and audit program provide for periodic scheduled audits or surveys of suppliers, the site procurement program, contractors, subcontractors, and others performing work. The audit and survey schedule is prepared and updated by Quality. Frequency of these surveys and audits is based upon the safety, complexity, and quality requirements, and as a minimum shall be in compliance with Reference 4.3.

5.6.3 When purchasing commercial-grade calibration services from calibration laboratories accredited by a nationally-recognized accrediting body, the accreditation process and accrediting body may be credited with carrying out a portion of the STPNOC's duties of verifying acceptability and effective implementation of the calibration service supplier's quality assurance program.

In lieu of performing an audit, accepting an audit by another licensee, or performing a commercial-grade survey, a documented review of the supplier's accreditation shall be performed by STPNOC. This review shall include, at a minimum, verification of the following:

- The accreditation is to ANSI/ISO/IEC 17025
- The accrediting body is either NVLAP or A2LA. The A2LA accreditation is recognized by NVLAP through the ILAC MRA.
- The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties. This requires the supplier to provide a measurement of collective uncertainty and obviates the need to impose the four-to-one ratio requirement discussed in NISTIR 6989.
- STPNOC is responsible for ensuring that the procured services are within the accredited scope of the NVLAP and A2LA certificates.

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6.0 DOCUMENTATION

6.1 Procedures which are generated as required by this chapter shall identify the records which are required to implement and document those activities. The records shall be controlled in accordance with Reference 4.7.

7.0 ATTACHMENTS

7.1 None