



10 CFR 50.54(a)(4)

Palo Verde Nuclear
Generating Station

Gregg R. Overbeck
Senior Vice President
Nuclear

TEL (623) 393-5148
FAX (623) 393-6077
102-05150-GRO/DWG
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Mail Station 7602
P.O. Box 52034
Phoenix, AZ 85072-2034

U. S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Mail Station P1-37
Washington, DC 20555-0001

Dear Sirs:

**Subject: Palo Verde Nuclear Generating Station (PVNGS)
Units 1, 2, and 3 Docket Nos. STN 50-528, 50-529 and 50-530
License Nos. NPF-41, NPF-51 and NPF-74
PVNGS Quality Assurance (QA) Program Reduction in Commitment**

Pursuant to 10 CFR 50.54(a)(4), Arizona Public Service Company (APS) hereby requests approval of a revision to the PVNGS QA Program that results in a reduction of commitment to the previously accepted quality assurance program. The proposed change is to provide for acceptance of accreditation to ANSI/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories", by a nationally-recognized accrediting body in lieu of a supplier audit, commercial-grade survey, or in-process surveillance during performance of the accredited calibration services. This method for qualifying the calibration supplier and for accepting their calibration services will be applied only to commercial-grade calibration services as defined by 10 CFR Part 21.

The enclosed justification is provided to demonstrate that acceptance of calibration services from suppliers with an accredited program meeting ANSI/ISO/IEC 17025, in conjunction with the commercial-grade procurement process, along with additional controls, will satisfy the pertinent requirements of 10 CFR 50, Appendix B, and provide an adequate level of quality control.

No commitments are being made to the NRC by this letter. Should you have any questions, please contact Thomas N. Weber at (623) 393-5764.

Sincerely,

A member of the **STARS** (Strategic Teaming and Resource Sharing) Alliance

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Reduction in Commitment to the PVNGS Quality Assurance (QA) Program
Page 2

Enclosure: Proposed Change to PVNGS QA Program

Attachment 1: Markup of the PVNGS UFSAR (Information Only)

cc:	B. S. Mallett	NRC Region IV Regional Administrator
	M. B. Fields	NRC NRR Project Manager
	N. L. Salgado	NRC Senior Resident Inspector for PVNGS
	A. V. Godwin	Arizona Radiation Regulatory Agency

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Reduction in Commitment to the PVNGS Quality Assurance (QA) Program
Page 3

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Bcc: T. N. Weber 7636
S. A. Bauer 7636
D. M. Baldwin 7996
D. R. Leech 7996
M. D. Carnes 7997
NOC 9046
M. K. Banks 7615
D. M. Smith 7602
C. D. Mauldin 7605
G. R. Overbeck 7602
J. M. Levine 9046
B. A. Pregulman 8695

STARS Distribution :

e-Mail
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 None

SOURCE DOCUMENTS

1. 10 CFR 50.54, Conditions of License
2. 10 CFR Part 21, Reporting of Defects and Noncompliance
3. 10 CFR 50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
4. ANSI/ISO/IEC 17025:1999, General Requirements for the Competence of Testing and Calibration Laboratories
5. NISTIR 6989, Comparison of ISO/IEC 17025 with the NUPIC Audit Checklist, May 2003
6. NRC Reg Guide 1.33, Quality Assurance Program Requirements (Operation), Revision 2, 1978
7. NRC Reg Guide 1.123, Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants, Revision 1 July 1977
8. NRC Reg Guide 1.144, Auditing of Quality Assurance Programs for Nuclear Power Plants, Revision 1 September 1980
9. ANS-3.2/ANSI 18.7-1976, Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants
10. ANSI N45.2-1971, Quality Assurance Program Requirements for Nuclear Power Plants

Proposed Change to PVNGS QA Program

1.0 Description of the Change

2.0 Reason for the Proposed Change

3.0 Basis for Concluding that the Revised Program Continues to Satisfy the Criteria of 10 CFR 50, Appendix B and the Previously Accepted Quality Assurance Program Commitments

3.1 Introduction

3.2 Review of 10 CFR 50, Appendix B, Criterion 1, Organization

3.3 Review of 10 CFR 50, Appendix B, Criterion 4, Procurement Document Control

3.4 Review of 10 CFR 50, Appendix B, Criterion 7, Control of Purchased Material, Equipment, and Services

3.5 Review of 10 CFR 50, Appendix B, Criterion 12, Control of Measuring and Test Equipment

3.6 Review of 10 CFR 50, Appendix B, Criterion 18, Audits

4.0 Conclusion

5.0 References

1.0 DESCRIPTION OF THE CHANGE

Arizona Public Service (APS) is proposing a change to the Palo Verde Nuclear Generating Station (PVNGS) Quality Assurance (QA) Program description to provide for acceptance of accreditation to ANSI/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories" (Reference 1), by a nationally-recognized accrediting body in lieu of a supplier audit, commercial-grade survey, or in-process surveillance during performance of the accredited calibration services. This method for qualifying the calibration supplier and for accepting their calibration services will be applied only to commercial-grade (as defined by 10 CFR Part 21) calibration services.

For the purposes of this change, nationally-recognized accrediting bodies include the National Voluntary Laboratory Accreditation Program (NVLAP) (Reference 2) and other accrediting bodies that have been recognized by NVLAP via a Mutual Recognition Agreement (MRA). The overall intent of the change is to take advantage of the current internationally-recognized standards and the nationally-recognized accreditation process when qualifying suppliers to perform calibration services for the nuclear industry. Proposed changes to the PVNGS QA Program, as described in the PVNGS Updated Safety Analysis Report (UFSAR) (Reference 6), are detailed below:

A. UFSAR Section 1.8, Conformance to NRC Regulatory Guides

1. Regulatory Guide 1.33, Quality Assurance Program Requirements (Operation) (Revision 2, February 1978)

In APS' response to this regulatory guide, the following clarification will be added:

Compliance with ANSI standards referenced throughout ANSI N18.7-1976/ANS-3.2 is addressed separately in APS' response to conformance with the regulatory guides listed in section C.2 of Regulatory Guide 1.33.

In addition, the following exception will be taken to ANSI N18.7:

When purchasing commercial-grade calibration services from certain accredited calibration laboratories, the procurement documents are not required to impose a quality assurance program consistent with ANSI N45.2-1971. Alternative requirements described in UFSAR Section 1.8 for Regulatory Guide 1.123 may be implemented in lieu of imposing a quality assurance program consistent with ANSI N45.2-1971.

2. Regulatory Guide 1.123, Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants (Revision 1, July 1977)

In APS' response to this regulatory guide, the following exception will be added regarding APS compliance with ANSI N45.2.13-1976:

B. Section 3.2.3

The requirements of this section are accepted with the following exception:

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 ANSI N45.2-1971. 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). In such cases, accreditation may be accepted in lieu of the Purchaser imposing a QA Program consistent with ANSI N45.2-1971, provided all the following are met:

- 1. The accreditation is to ANSI/ISO/IEC 17025.*
- 2. The accrediting body is either NVLAP or an accrediting body recognized by NVLAP through an MRA.*
- 3. The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.*
- 4. The purchase documents impose additional technical and administrative requirements, as necessary, to satisfy APS QA Program and technical requirements.*
- 5. The purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.*

3. Regulatory Guide 1.144, Auditing of Quality Assurance Program for Nuclear Power Plants (Revision 1, September 1980)

In APS' response to this regulatory guide, the following interpretation will be added:

D. Regulatory Guide 1.144, Section C.3.b(2)

The requirements of this section are accepted with the following interpretation:

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.

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).

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

- 1. The accreditation is to ANSI/ISO/IEC 17025.*
- 2. The accrediting body is either NVLAP or an accrediting body recognized by NVLAP through an MRA.*
- 3. The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.*

B. UFSAR Section 17.2.3.3.2, Qualification and Selection of External Organizations

1. In section 17.2.3.3.2.2 regarding prospective suppliers, the following criteria will be added as a basis for qualification:

D. The supplier is providing commercial-grade calibration services and is accredited by a nationally-recognized accrediting body as described in the APS responses to NRC Regulatory Guides 1.123 and 1.144 that are documented in Section 1.8 of the UFSAR. For suppliers of commercial-grade calibration services with accreditation by a nationally-recognized accrediting body, a documented review of the supplier's accreditation by the purchaser may be used in lieu of inspections or tests following delivery or in-process surveillances during performance of the service. This review shall include, at a minimum, all of the following:

- 1. The accreditation is to ANSI/ISO/IEC 17025.*
- 2. The accrediting body is either NVLAP or an accrediting body recognized by NVLAP through an MRA.*
- 3. The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.*

2.0 REASON FOR THE PROPOSED CHANGE

As stated in a letter from APS to the NRC on October 3, 1997 (Reference 3), APS has experienced cases where calibration service providers on the APS Approved Vendors List (AVL) have utilized NVLAP accredited laboratories for calibration/ verification of their primary standards without performing an audit of the NVLAP accredited laboratory. These AVL vendors have not undertaken any additional verification efforts in the absence of an audit.

APS could not find a regulatory allowance that would permit such calibration service providers that maintain a 10 CFR 50, Appendix B Quality Assurance Program to not have to audit sub-tier calibration service providers under such circumstances. As a result, APS has had to send the affected measuring and test equipment (M&TE) to other vendors which can meet our requirements. However, as recognized by the industry, this is increasingly becoming a serious hardship as the number of vendors that can meet the quality assurance requirements have dramatically dropped.

3.0 BASIS FOR CONCLUDING THAT THE REVISED PROGRAM CONTINUES TO SATISFY THE CRITERIA OF 10 CFR 50, APPENDIX B AND THE PREVIOUSLY ACCEPTED QUALITY ASSURANCE PROGRAM COMMITMENTS

3.1 Introduction

In the October 3, 1997 letter, APS requested that the NRC review the NVLAP accreditation process for the purpose of providing regulatory guidance or rulemaking regarding its use in the nuclear industry, specifically with regard to the need to audit accredited laboratories. In a letter dated October 20, 2000 (Reference 4), the NRC replied to APS with a list of issues that needed to be resolved prior to the NRC completing their review of the use of NVLAP. Subsequently, in a letter dated January 26, 2001 (Reference 5), the NRC informed APS that their review was concluded and that the issues identified in the October 20, 2000 letter should be addressed prior to receiving Commission approval of the use of NVLAP.

This submittal proposes a different approach than that submitted by APS on October 3, 1997. Rather than requesting the NRC to endorse NVLAP through regulatory guidance or rulemaking, APS is requesting that the NRC approve specific changes to the PVNGS QA Program within the existing regulatory framework of quality assurance requirements (i.e., in accordance with 10 CFR 50.54(a)(4)). This requested change also differs from the previous request in that it is limited to commercial-grade calibration services. The proposed change is considered to be enveloped by the commercial-grade procurement process currently described in the PVNGS QA Program. However, it involves a reduction in QA Program commitment because it provides alternatives to current commitments related to specific NRC Regulatory Guides and associated industry standards as discussed in Sections 1.8 and 17.2B of the PVNGS UFSAR (Reference 6). Refer to Attachment 1 for a draft mark-up of the UFSAR.

Nuclear industry representatives, the NRC, and members of the National Institute of Standards and Technology (NIST) have interacted for some time regarding the acceptability of using accreditation in lieu of licensee or supplier audits. As documented in SECY 03-0117, "Approaches for Adopting More Widely Accepted International Quality Standards" (Reference 7), the NRC reviewed ISO 9001, "Quality Management Systems - Requirements" and suggested four approaches for potential implementation of ISO 9001. In approach #4, the NRC suggested that the use of suppliers with ISO 9001-2000 certification by licensees would be appropriate for replacement parts purchased as commercial-grade items.

In accordance with the NIST Handbook (Reference 8), NVLAP uses the ANSI/ISO/IEC 17025 standard (Reference 1) as the basis for the accreditation of testing and calibration laboratories. ANSI/ISO/IEC 17025 incorporates those requirements of ISO 9001 that are relevant to the scope of testing and calibration services that are covered by a laboratory's quality system.

The Nuclear Procurement Issues Committee (NUPIC), under the joint utility audit program, audits and approves most suppliers of replacement parts provided to operating US nuclear plants. NUPIC provides a consistent means for evaluating and auditing these suppliers. Recent industry interactions resulted in an analysis of the "gaps" between the NUPIC commercial-grade survey checklist and ANSI/ISO/IEC 17025 requirements. This gap analysis was formally published by NIST as NISTIR 6989, "Comparison of ISO/IEC 17025 with the NUPIC Audit Checklist" (Reference 9).

This comparison demonstrates, with only a few minor exceptions, that ANSI/ISO/IEC 17025 encompasses the quality assurance program requirements imposed by licensees or their suppliers in order to meet the pertinent requirements of 10 CFR 50, Appendix B. Additionally, the documented accreditation process and assessor qualification requirements ensure that an accredited calibration supplier has effectively implemented the requirements of ANSI/ISO/IEC 17025 for their scope of accreditation.

Specific "gaps" identified in NISTIR 6989 include:

- a) As-found data is not required to be reported unless adjustments are made.
- b) A minimum uncertainty ratio is not specified (standard $\leq 0.25\%$ of Instrument under Test)
- c) The standard does not require the supplier to report which standards were used to perform the calibration.

The shortcomings identified in NISTIR 6989 can be addressed by the purchaser imposing additional, specific requirements via the procurement documents when necessary to meet licensee specific regulatory or technical requirements. The proposed QA Program wording changes provide for imposing these additional requirements, when necessary.

In general, a calibration service provider's QA program that has been accredited by the nationally-recognized accrediting body and has been verified as meeting ANSI/ISO/IEC 17025, is considered to be a technically-rigorous program that supports licensees and their approved suppliers in meeting the pertinent quality assurance program provisions of 10 CFR 50, Appendix B (as they apply to commercial-grade calibration services). It should be recognized that accreditation is a nationally-recognized commercial process and that it is not specifically designed to verify implementation of nuclear-industry-specific standards, regulations, or individual NRC licensee requirements.

APS is ultimately responsible for activities affecting quality at PVNGS, including those activities delegated to the suppliers of items and/or services. APS and its approved suppliers will continue to impose appropriate regulatory, technical, and quality requirements on their suppliers and sub-suppliers. In this respect, the changes proposed have minimal impact on current implementation of the PVNGS QA Program. However, certain commitments related to the criteria of 10 CFR 50 Appendix B are affected. The predominant criteria of 10 CFR 50, Appendix B, that are related to the proposed PVNGS QA Program change and which may be affected are Criterion 1, 4, 7, 12, and 18. A discussion on how APS will continue to comply with each of these criterion follows.

3.2 Review of 10 CFR 50, Appendix B, Criterion 1, Organization

Criterion 1 requires that the licensee retain responsibility for the establishment and execution of the quality assurance program as it applies to the design, fabrication, construction, and testing of safety-related structures, systems and components of the facility. The proposed change does not alter this commitment.

APS will continue to retain overall responsibility for assuring that purchased calibration services will meet applicable technical and regulatory requirements and that reasonable assurance of quality is provided. APS will require that the calibration service provider have a program that is accredited to ANSI/ISO/IEC 17025 and will impose additional technical or quality assurance program requirements when necessary to meet PVNGS regulatory requirements and commitments.

Criterion 1 also allows for the delegation of authorities and duties for carrying out portions of the quality assurance program to others. Delegation of authorities and duties is affected in two ways by the proposed change.

1. The actual commercial-grade calibration work is delegated to the calibration service supplier via the procurement documents and purchasing requirements as discussed in Criteria 4 and 7. The overall program controls are unchanged regarding this aspect of delegation of authority as discussed later under Criteria 4 and 7.
2. A portion of the quality assurance process, specifically that of assessing implementation of the quality assurance program by the calibration service provider is in effect "delegated" to the accreditation process and the accrediting body. Criterion 1 requires that this delegation be clearly established and delineated in

writing. Changes to the text of the PVNGS QA Program will specifically provide for delegation of this function in writing.

APS will continue to retain responsibility for the establishment and execution of quality assurance in regard to commercial-grade calibration services. The delegation of authority and duties affecting this activity will continue to be delineated by APS in writing. Therefore, the applicable requirements of 10 CFR 50 Appendix B, Criterion 1 will continue to be met.

3.3 Review of 10 CFR 50, Appendix B, Criterion 4, Procurement Document Control

Criterion 4 requires that measures be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of services, whether purchased by the applicant or by its contractors or subcontractors.

Regarding procurement document controls to meet Appendix B Criterion 4 requirements, APS is committed to Revision 2 of NRC Regulatory Guide 1.33, "Quality Assurance Program Requirements (Operation)" as documented in Section 1.8 of the PVNGS UFSAR. Reg Guide 1.33 endorses ANSI N18.7-1976, "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants" for overall quality assurance program requirements. Section 5.2.13.1 of ANSI N18.7-1976 states that, to the extent necessary, procurement documents shall require suppliers to provide a quality assurance program consistent with the pertinent requirements of ANS N45.2-1971, Quality Assurance Program Requirements for Nuclear Power Plants.

APS will continue to impose the pertinent requirements of 10 CFR 50, Appendix B on approved and accredited suppliers of commercial-grade calibration services. However, the methods will change for evaluating and selecting suppliers and for how the pertinent requirements of 10 CFR 50, Appendix B, are imposed on these accredited suppliers.

As an alternative to requiring consistency with ANS N45.2-1971, APS proposes the option for procurement documents to require that the commercial-grade calibration service supplier provide a quality assurance program that is consistent with the requirements of ANSI/ISO/IEC 17025 and that the accreditation is by a nationally-recognized accrediting body (e.g., NVLAP).

This change constitutes a reduction in the level of APS' commitment to Regulatory Guide 1.33 and ANSI N18.7-1976. However, as demonstrated in Section 3.1 of this letter, the alternative measures assure an equivalent level of quality control and, therefore, the applicable requirements of 10 CFR 50 Appendix B, Criterion 4 will continue to be met.

3.4 Review of 10 CFR 50, Appendix B, Criterion 7, Control of Purchased Material, Equipment, and Services

Criterion 7 requires that measures be established to assure that purchased material, equipment, and services conform to the procurement documents. These measures include, as appropriate, source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.

Regarding the control of purchasing material to meet Appendix B Criterion 7 requirements, APS is committed to Rev 1 of NRC Regulatory Guide 1.123, "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants" as documented in Section 1.8 of the PVNGS UFSAR. Regulatory Guide 1.123 endorses the use of ANSI N45.2.13-1976, "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants" for complying with the pertinent quality assurance requirements of Appendix B to 10 CFR Part 50. Section 10.3 of ANSI N45.2.13-1976 provides guidance on methods used by Purchasers to accept items or services from a Supplier. Section 10.3.5 of ANSI N45.2.13-1976 provides additional guidance regarding acceptance of services only. It states, in part:

In certain cases involving procurement of services only ... the Purchaser may accept the service by any or all of the following methods:

- a. *Technical verification of data produced.*
- b. *Surveillance and/or audit of the activity.*
- c. *Review of objective evidence for conformance to the procurement document requirements such as certifications, stress reports, etc.*

APS proposes that for commercial-grade calibration service providers with accredited programs, the reliance on this accreditation process and accrediting body provides for the technical verification of data produced as well as for the surveillance and/or audit of the commercial-grade calibration activity (items a. and b. above).

In the case of commercial-grade calibration services, APS or the APS-approved Appendix B suppliers using the accredited laboratories will be responsible for reviewing objective evidence for conformance to the procurement documents, such as review of documentation to validate the calibration service provider's accreditation and review of the actual calibration certificates provided by the calibration laboratory. APS or the APS-approved Appendix B suppliers may also require the calibration laboratory to provide "certificates of conformance" to the requirements of the procurement documents as described in ANSI N45.2.13-1976, Section 10.3.3.

However, APS or the APS-approved Appendix B suppliers will not directly perform technical verification of data produced nor will they be required to perform direct surveillance and/or audit of the accredited calibration laboratory activities.

Acceptance of calibration services by the methods described in Sections 10.3.2 and 10.3.4 of ANSI N45.2.13-1976 (i.e., by receiving inspection and/or post-installation test) are considered to be impractical for supplier's of calibration services, since they are not providing items (structures, systems, components, or spare parts) that can be directly inspected or tested.

APS proposes that for commercial-grade calibration services, accreditation to ANSI/ISO/IEC 17025 and the audits/surveillance provided by the nationally-recognized accrediting body may be substituted in lieu of surveillance by APS during performance of the commercial-grade calibration service. The proposed change provides additional requirements for APS to verify the commercial-grade calibration service provider's accreditation and that their scope of accreditation covers the needed measurement parameters, ranges, and uncertainties.

This constitutes a reduction in the level of commitment related to Regulatory Guide 1.123 Revision 1 and ANSI N45.2.13-1976. As discussed in Section 3.1 of this letter, accreditation to ANSI/ISO/IEC 17025 provided by the nationally-recognized accrediting body along with additional controls, will provide sufficient control for ensuring acceptability of the commercial-grade calibration service equivalent to that required by ANSI N45.2.13-1976. Therefore, the requirements of 10 CFR 50 Appendix B, Criterion 7 will continue to be met.

3.5 Review of 10 CFR 50, Appendix B, Criterion 12, Control of Measuring and Test Equipment

Criterion 12 requires that measures be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

Regarding the control of measuring and test equipment to meet Appendix B Criterion 12 requirements, APS is further committed to Rev 1 of NRC Regulatory Guide 1.123 (which endorses ANSI N45.2.13-1976) as documented in Section 1.8 of the PVNGS UFSAR. Section 7.4.2 of ANSI N45.2.13-1976 states that "when inspection, measuring, and test equipment are found to be out of calibration, an evaluation shall be made and documented of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested."

However, as one of the few issues identified in NISTIR 6989, ANSI/ISO/IEC 17025 does not require that the accredited supplier provide as-found calibration data when the item being calibrated is found to be out-of-tolerance. Since this data is needed to support APS or the APS-approved Appendix B supplier in performing the required evaluations, an additional requirement will be imposed via the procurement documents to require that the accredited supplier provide as-found calibration data when the item being calibrated is found to be out-of-tolerance. The reporting of as-found calibration data for out-of-tolerance items will also support APS or the APS-approved Appendix B supplier

in performing evaluations necessary to meet their obligations for reporting of defects and non-compliances as required by 10 CFR Part 21.

Since APS will impose this specific reporting requirement in procurement documents, and APS or the APS-approved Appendix B supplier will continue to maintain the responsibility for ensuring an appropriate evaluation is made, the requirements of Section 7.4.2 of ANSI N45.2.13-1976 are maintained. Therefore, the requirements of 10 CFR 50 Appendix B, Criterion 12 will continue to be met.

3.6 Review of 10 CFR 50, Appendix B, Criterion 18, Audits

Criterion 18 requires that a comprehensive system of planned and periodic audits be carried out by appropriately trained personnel not having direct responsibility in the areas being audited.

Regarding the performance of audits to meet Appendix B Criterion 18 requirements, APS is committed to Rev 1 of NRC Regulatory Guide 1.144, "Auditing of Quality Assurance Program for Nuclear Power Plants" as documented in Section 1.8 of the PVNGS UFSAR. Regulatory Guide 1.144 endorses the use of ANSI N45.2.12-1977, "Auditing of Quality Assurance Programs for Nuclear Power Plants".

Regulatory Position C.3.b.(2) of Regulatory Guide 1.144 discusses the performance of audits by the Purchaser (APS) in accordance with Section 4 of ANSI/ASME N45.2.12-1977. This position includes provisions for accepting audits by other purchasers (licensees) in order to reduce the number of external audits of the supplier. However, it provides no discussion regarding the acceptance of accreditation in lieu of separate audits by the purchasers or their representatives (e.g., NUPIC).

APS proposes an exception that would allow the acceptance of ANSI/ISO/IEC 17025 accreditation in lieu of separate audits by the purchasers or their representatives for commercial grade calibration services. When purchasing calibration services from accredited calibration laboratories, the accreditation process and accrediting body would be credited, in part, with carrying out a portion of the Purchaser's responsibility for auditing of the supplier's quality assurance program and implementation. In lieu of performing an audit or accepting an audit by another licensee, a documented review of the supplier's accreditation shall be performed by the Purchaser.

This review shall include, at a minimum, all of the following:

1. The accreditation is to ANSI/ISO/IEC 17025.
2. The accrediting body is either the NVLAP or an accrediting body recognized by NVLAP through an MRA.
3. The published Scope of Accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.

The PVNGS Nuclear Assurance organization will continue to provide independent audits of the procurement process, including the process for selecting and qualifying calibration service providers. However, a portion of the responsibility for audit and oversight of the accredited calibration laboratory's quality assurance program is delegated to the accreditation process and accrediting body.

This constitutes a reduction in the level of commitment related to Regulatory Guide 1.144 Revision 1 and ANSI N45.2.12-1977. As discussed in Section 3.1 of this letter, accreditation to ANSI/ISO/IEC 17025 provided by the nationally-recognized accrediting body along with additional controls, will provide sufficient confidence that applicable elements of the calibration facility's quality assurance program have been developed, documented, and effectively implemented in accordance with the specified requirements. Use of the accreditation process would provide equivalent measures to that required by ANSI N45.2.12-1977 and Regulatory Guide 1.144. Therefore, the requirements of 10 CFR 50 Appendix B, Criterion 18 will continue to be met.

4.0 CONCLUSION

Based on the justification for the alternative implementation provided in this submittal, the PVNGS QA program, as modified, will continue to satisfy the criteria of Appendix B to 10 CFR Part 50, and provide an equivalent, and therefore acceptable, level of quality control.

5.0 REFERENCES

1. ANSI/ISO/IEC 17025:1999, General Requirements for the Competence of Testing and Calibration Laboratories
2. 15 CFR Part 285, National Voluntary Laboratory Accreditation Program
3. APS Letter to NRC, Request for NRC Review of National Institute of Standards and Technology (NIST) National Voluntary Laboratory Accreditation Program (NVLAP), Dated October 3, 1997
4. NRC Letter to APS, Palo Verde Nuclear Generating Station, Units 1, 2, and 3 - Review of the National Voluntary Laboratory Accreditation Program (TAC No. MA9159), Dated October 20, 2000
5. NRC Letter to APS, Palo Verde Nuclear Generating Station, Units 1, 2, and 3 Re: National Institute of Standards and Technology National Voluntary Laboratory Accreditation Program (TAC Nos. MA9159, MB0577, AND MB0578), Dated January 26, 2001
6. PVNGS Updated Final Safety Analysis Report, Revision 12
7. SECY 03-0117, Approaches for Adopting More Widely Accepted International Quality Standards, the NRC, Dated July 9, 2003

8. NIST Handbook 150, (2001 Edition), National Voluntary Laboratory Accreditation Program Procedures and General Requirements
9. NISTIR 6989, Comparison of ISO/IEC 17025 with the NUPIC Audit Checklist, May 2003