October 20, 2000

Mr. Gregg R. Overbeck
Senior Vice President, Nuclear
Arizona Public Service Company
P. O. Box 52034
Phoenix, AZ 85072-2034

SUBJECT: PALO VERDE NUCLEAR GENERATING STATION, UNITS 1, 2, AND 3 - REVIEW OF THE NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM (TAC NO. MA9159)

Dear Mr. Overbeck:

By letter dated October 3, 1997, Arizona Public Service Company (APS) requested the U.S. Nuclear Regulatory Commission's (NRC's) review of the National Institute of Standards and Technology's National Voluntary Laboratory Accreditation Program (NVLAP) to determine if it contains sufficient controls so that the NRC's licensees, and 10 CFR Part 50, Appendix B-audited calibration service providers would not be required to audit NVLAP accredited laboratories. APS requested that the review be performed in accordance with the National Technology Transfer and Advancement Act of 1995 (Public Law 104-113).

Enclosed is a list of issues that will require resolution before the NRC staff can complete its review of the NVLAP accreditation process.

We would be willing to meet with your staff to discuss these issues. If you have any questions regarding this matter, please contact me at (301) 415-8439.

Sincerely,

/RA/

Girija Shukla, Project Manager, Section 2
Project Directorate IV & Decommissioning
Division of Licensing Project Management
Office of Nuclear Reactor Regulation

Docket Nos. STN 50-528, STN 50-529,
and STN 50-530

Enclosure: List of issues

cc w/encl: See next page

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LIST OF ISSUES RELATED TO

NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM (NVLAP)

The NRC staff has identified a number of differences, as noted below, between the NVLAP program and 10 CFR Part 50, Appendix B requirements. These differences will need to be reconciled before the staff can accept the licensee's proposal not to audit NVLAP accredited laboratories.

1. **10 CFR PART 21**

It does not appear that the NVLAP accreditation process includes provisions for requiring compliance with the reporting requirement of 10 CFR Part 21. It is also not clear how licensees will ensure that NVLAP accredited laboratories are aware of this requirement and are required to comply with it.

2. **QUALITY ASSURANCE (QA) PROGRAM IMPLEMENTATION**

The regulation at 10 CFR 50.34(b)(6)(ii) requires, in part, that licensees provide managerial and administrative controls that describe how the applicable requirements of Appendix B will be satisfied. For suppliers of nuclear services, this is generally accomplished either by licensee-imposed QA programs or verification that a supplier's QA program complies with 10 CFR Part 50, Appendix B. The NVLAP accreditation process does not appear to include provisions for requiring verification that suppliers have implemented QA programs in compliance with 10 CFR Part 50, Appendix B.

3. **ANSI/NCSL Z540-1-1994**

ANSI/ASME standards NQA-1-1983 (design/construction) and N45.2-1977 (operations) have been conditionally endorsed by the NRC as describing acceptable methods for complying with the provisions of 10 CFR Part 50, Appendix B. The primary basis standard for NVLAP accreditation is ANSI/NCSL Z540-1-1994. The requirements of this standard do not appear to be as rigorous as ANSI/IEEE 498, which invokes NQA-1 for applicable QA requirements. Some of the issues with ANSI/NCSL Z540-1 include:

- No imposition of QA program requirements on the supplier,
- As-found/as-left condition reportable to the licensees only if deemed significant, and
- 4:1 accuracy acceptance criterion 12.6 of Standard Review Plan 17.1 (NUREG-0800) does not appear to be adhered to.

4. **NVLAP ACCREDITATION PROCESS**

There are several differences when comparing the NVLAP accreditation process to NRC requirements and QA-related guidance. These differences include:

4.1 The accreditation process appears to select assessors and evaluators based on their professional and academic achievements, experience in the field of testing or calibration, and management experience. Although this approach may be adequate from a technical perspective, it may not be sufficient for assessing whether assessors/evaluators are knowledgeable of nuclear QA provisions to ensure compliance with 10 CFR Part 50, Appendix B requirements.

4.2 Records maintained by the NVLAP-accredited labs may not meet the recordkeeping requirements of ANSI N45.2.9, as endorsed by Regulatory Guide N18.7-1976.

4.3 Internal audit programs of accredited labs may not meet the regulatory requirements of ANSI 45.2.12-1977 and ANSI N45.2.23-1978, as endorsed by Regulatory Guide N18.7-1976.

4.4 Qualifications and Training of personnel performing calibration work may not be adequate to perform calibration work for nuclear licensees that complies with the regulatory requirements.

5. EXPECTATIONS VERSUS REQUIREMENTS (ENFORCEMENT)

The NVLAP accreditation program is based on voluntary implementation by accredited labs. Once accredited, an on-site assessment is conducted only every 2 years, and the scope of this assessment may consist only of checking a few designated items. This approach appears to be considerably less rigorous than the Nuclear Procurement Issues Committee audits or periodic audits by the licensee, and the basis for withdrawal of accreditation is not clear. It appears that there is a potential that noncompliances could continue to exist over extended periods of time before the accreditation is finally withdrawn, which could allow potentially unqualified labs to continue performing calibration work for nuclear licensees.

6. PROGRAM OVERSIGHT

The list of NVLAP-accredited labs is extensive. It is not clear how the oversight group, composed of volunteers from industry and government, will assure that the listed labs remain fully qualified to perform calibration work for NRC-regulated licensees, i.e., whether the calibration work meets all applicable NRC regulations. Since the program is currently not subject to NRC review and inspections, compliance with the NRC regulation is an issue that needs to be addressed.