May 14, 2008

Mr. Patrick V. McCullen
Vice President
International Accreditation Service, Inc.
5360 Workman Mill Road
Whittier, CA 90601

SUBJECT: REPLY TO YOUR LETTER DATED MARCH 3, 2008, SEEKING ASSISTANCE IN ACCEPTING INTERNATIONAL ACCREDITATION SERVICE, INC.

Dear Mr. McCullen:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am responding to your letter dated March 3, 2008. You requested that NRC provide assistance in accepting International Accreditation Service, Inc. (IAS) as an acceptable accreditation body (AB) for the accreditation of commercial calibration laboratories as stipulated in International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025, "General Requirements for the Competence of Testing and Calibration Laboratories." You stated that IAS accreditations are equivalent to those issued by the National Voluntary Laboratory Accreditation Program (NVLAP) and the American Association for Laboratory Accreditation (A2LA), whose programs are recognized by the NRC.

By way of background, on September 28, 2005, the NRC approved a request from Arizona Public Service Company (APS), in accordance with the regulations in Section 50.54(a)(4) of Title 10 of the *Code of Federal Regulations* (10 CFR), which proposed a change to the Quality Assurance Program (QAP) for the Palo Verde Nuclear Generating Station (PVNGS). The proposed change provided for use of accreditation of commercial-grade (as defined by 10 CFR Part 21, "Reporting of Defects and Noncompliance") calibration services by a nationally-recognized AB, in lieu of a supplier audit, commercial-grade survey, or in-process surveillance, using procedures consistent with international standards and guidelines, specifically those found in ISO/IEC 17025. In its proposed change to the QAP, APS stated that nationally-recognized ABs included NVLAP and others recognized by NVLAP through a Mutual Recognition Arrangement (MRA). The staff understood this statement to include other ABs accepted as signatories (full members) to the International Laboratory Accreditation Cooperation (ILAC) MRA.

In the safety evaluation (SE) for the proposed change, the staff discussed NVLAP and A2LA only in the context of NRC's overall approval of the APS request. This was not an endorsement or approval of such organizations, only recognition that the NRC finds the NVLAP and A2LA accreditation programs for calibration services to be acceptable. As such, the staff concluded the following: (1) both accreditation programs constitute an acceptable alternative to APS's provisions for qualification of commercial-grade calibration services provided that the bases of the NRC approval are acceptable to the licensee's facility, and (2) the PVNGS QAP, as described in Section 17 of the Updated Final Safety Analysis Report, continues to satisfy the requirements of Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." In the SE, the staff limited its review and approval of the proposed QAP change to NVLAP and A2LA since both organizations were U.S.-based signatories to the ILAC MRA at the time of the staff's review. Since then, the NRC has extended recognition to the commercial calibration laboratory accreditation programs of ACLASS Accreditation Services and Laboratory Accreditation Bureau which became U.S.-based signatories to the ILAC MRA subsequent to the issuance of the SE.

You also stated that several IAS-accredited laboratories, which provide calibration and testing services to the nuclear industry, have encountered difficulties in gaining acceptance of their services despite their IAS-accreditation and status as an ILAC signatory. Although the NRC recognizes that the ABs discussed above provide alternatives to the methods used by licensees to qualify suppliers of commercial-grade calibration services, each nuclear power plant licensee has the responsibility to decide which suppliers to select, approve, and maintain. Lastly you stated that based on information you received from ILAC, IAS advised its accredited laboratories to include certain information in their certificates/reports presumably required by the NRC's "Nuclear Caveat" for all work related to the nuclear industry, and you question whether this caveat is an NRC requirement.

The NRC does not have a "nuclear caveat" nor is this term referred to in any NRC regulation. The staff reviewed the information provided by ILAC to IAS and offers the following: (1) the staff's SE for the APS alternative discussed several differences that were identified in a gap analysis published by the National Institute of Standards and Technology (NIST) in May 2003. NIST Interagency Report (NISTIR) 6989, "Comparison of ISO/IEC 17025 with the Nuclear Procurement Issues Committee (NUPIC) Audit Checklist," identified several administrative requirements that were not addressed in ISO/IEC 17025, and may require a licensee to impose, in the procurement documents, additional technical and quality requirements on their suppliers and sub-suppliers to continue to comply with specific technical or regulatory requirements, specifically 10 CFR 50, Appendix B, (2) these differences discussed in (1) above, are also discussed in the staff's SE and appear to be the same as the four additional requirements, or "nuclear caveat," provided by ILAC to IAS, and (3) although these items do not constitute specific NRC requirements, the discussion of them in the SE forms the clarifying bases for the staff's acceptance of the APS alternative.

In conclusion, based on our understanding of the ILAC accreditation process, and IAS's status as a U.S.-based signatory to the ILAC MRA, the NRC considers IAS to be another alternative to the methods used by licensees to qualify commercial-grade calibration service suppliers.

Should you have any questions, please contact Dale Thatcher at (301) 415-3260.

Sincerely,

/RA/

Patrick L. Hiland, Director
Division of Engineering
Office of Nuclear Reactor Regulation

In conclusion, based on our understanding of the ILAC accreditation process, and IAS's status as a U.S.-based signatory to the ILAC MRA, the NRC considers IAS to be another alternative to the methods used by licensees to qualify commercial-grade calibration service suppliers.

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Sincerely,

Patrick L. Hiland, Director
Division of Engineering
Office of Nuclear Reactor Regulation

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