

April 30, 2015

Mr. Marcus Nichol, Senior Project Manager,  
Quality Issues and Licensing Actions  
Nuclear Energy Institute  
Nuclear Generation Division  
1776 I Street, NW  
Washington, DC 20006-3708

SUBJECT: QUALITY ASSURANCE PROGRAM REQUIREMENTS FOR NATIONAL  
METROLOGY INSTITUTES AS SUPPLIERS OF PRIMARY REFERENCE  
STANDARDS AND CALIBRATION

Dear Mr. Nichol:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am responding to your letter dated June 4, 2014, regarding your request for clarification on NRC's position on the quality assurance (QA) program requirements for international National Metrology Institutes (NMIs) as suppliers of primary reference standards and calibration services. You stated in your letter that for the National Institute of Standards and Technology (NIST), the domestic NMI, the NRC does not require licensees and suppliers to assure that NIST has a QA program that meets the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities" as stated in a letter dated August 24, 1983.<sup>1</sup> You suggested that the NRC evaluate the ability to use primary standards and calibration services from international NMIs without the need to perform an audit or commercial-grade survey of their QA program, such as the current process when procuring primary reference standards and calibration services from NIST.

NIST is a member of the International Bureau of Weights and Measures (BIPM). The BIPM is an international organization that ensures world-wide uniformity of measurements and their traceability to the International System of Units. NIST and many other international NMIs are signatories to the BIPM's International Committee for Weights and Measures Mutual Recognition Agreement (CIPM MRA), which establishes the degree of equivalence and consistency of national measurement standards maintained by NMIs. Equivalence and consistency are established based upon comparison across a set of key quantitative measures, a suitable way of assuring quality, and participation in appropriate supplementary comparisons. The CIPM MRA recognizes the degree of equivalence of national measurement standards, and the validity of calibration and measurement certificates issued by participating NMIs. Thus, NMIs that are CIPM MRA signatories are nationally and internationally recognized with proven

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<sup>1</sup> "QA Program Requirements for Suppliers of Calibration Services," NRC Letter from Uldis Potapovs, Chief Vendor Program Branch to J.L. Wood, Bingham-Williamette Company, August 24, 1983.

abilities and disciplines, similar to NIST. In addition, NMIs are government institutions and do not permit customers to independently audit or survey their QA programs.

Based on the above, with regards to the use of domestic and international NMIs as suppliers of primary reference standards and calibration services, the NRC's position is as follows:

Licensees and suppliers of basic components may procure primary reference standards and calibration services from NMI's that are signatories to the CIPM MRA without the need to perform an audit or a commercial-grade survey as the NMIs are organizations with proven abilities and disciplines. However, licensees and suppliers of basic components are still responsible for: (1) ensuring that the appropriate technical requirements are included in the procurement documents, and (2) performing receipt inspections to ensure that the procurement document requirements are met. Furthermore, it is not necessary for licensees and suppliers of basic components to invoke the requirements of Appendix B to 10 CFR Part 50 or 10 CFR Part 21, "Reporting of Defects and Noncompliance," in the procurement documents for primary reference standards and calibration services.

Sincerely,

*/RA/*

Edward H. Roach, Chief  
Mechanical Vendor Inspection Branch  
Division of Construction Inspection  
and Operational Programs  
Office of New Reactors

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