February 11, 2018

Comments on NIST Special Publication 2000-01

In the Matter of:

ABC's of Conformity Assessment – *DRAFT*

Introduction – The American Association for Laboratory Accreditation (A2LA) is a nonprofit, non-governmental, public service, membership society. A2LA provides comprehensive services in conformity assessment accreditation and related training. Services are available to any type of organization, be it private or government. A2LA's accreditation programs are based on internationally accepted criteria for competence (e.g. ISO/IEC 17025, ISO/IEC 17020, etc.).

A2LA's mission is to provide independent, world-class accreditation and training programs that inspire confidence in the quality of services and acceptance of results from accredited organizations.

We appreciate the opportunity to provide comments on the *NIST Special Publication 2000-01, The ABC's of Conformity Assessment* (DRAFT) and are in strong support of a majority of the changes presented. We offer the following comments, organized according to line numbering within the DRAFT, in an effort to strengthen and clarify areas of concern identified by our organization.

Comment #1: Line 194-196 – Upon review the referenced sentence appears to be missing a 'not.' "The agreement requires that conformity assessment procedures be "prepared, adopted and applied with a view to, or with the effect of, creating unnecessary obstacles to international trade";

Comment #2: Line 264 – The final sentence of this paragraph refers to requirements that organizations meet but does not clarify what these requirements are and in general, the sentence does not appear to clearly relate to the subject of the paragraph. The following revision is suggested: "The Accreditation process assesses an organization's conformity assessment process, infrastructure, and results to ensure the organization meets requirements for conformity assessment and ensures consistency between organizations";

Comment #3: Line 274 – Figure 2 does not include reference to ISO/IEC 17024 certification bodies; however, section 3.4.2 is dedicated to the discussion of ISO/IEC 17024 personnel certification. Suggest revision of the table to include reference to ISO/IEC 17024;

Comment #4: Line 283 – We believe the correct 'ISO' reference to ISO/IEC 17000:2004 is ISO 17000, not ISO 170000;

5202 Presidents Court, Suite 220 | Frederick, MD 21703-8515 | Phone: 301 644 3248 | Fax: 240 454 9449 | www.A2LA.org

Comment #5: Line 316 – We believe the correct 'ISO' reference to ISO/IEC 17000:2004 is ISO 17000, not ISO 170000;

Comment #6: Line 341 – In regard to section 3.3 Testing, we recommend including ISO 15189:2012 *"Medical Laboratories-Requirements for quality and competence"*. ISO 15189 is based on ISO/IEC 17025 and ISO 9001 but it specifies requirements for competence and quality that are particular to medical laboratories. Although it is a regulatory requirement for laboratories conducting testing on samples derived from the human body to be CLIA certified; many medical laboratories find value in also holding accreditation to ISO 15189 because of the rigorous management system requirements that are absent from the CLIA regulations. Additionally, as emphasized in this document, Lines 232-236, "standards should be clearly and concisely written, readily understood…" which ISO 15189 meets;

Comment #7: Line 356 – We recommend removing 'all or in part' from the 2nd sentence to 'The test data developed is used to determine whether…' as this statement makes it seem as if one could pick and choose which data in the test report they can use in order to meet their needs. There has been concern amongst regulators, user groups and accreditation bodies that users of the test data are only selecting the 'passing' data from a test report in order to attempt to get their test items approved;

Comment #8: Line 360 – We recommend flip-flopping the sentences in line 360 and in line 361 as there are many more private sector laboratories than there are government supported/related laboratories;

Comment #9: Line 364 – We recommend changing '… laboratories conduct tests **to** received…' to '… laboratories conduct tests **on** received…';

Comment #10: Line 366 – Your statement '*Testing laboratories have no control over whether the sample represent the entire production population, or if they are testing only 'golden samples'* is not always true. ISO/IEC 17025 is written in a manner in which the test laboratory may be totally responsible for the sampling aspects, which would then allow the laboratory to have total control over the test sample(s);

Comment #11: Line 387 and 389 – We recommend that reference ISO/IEC 17065:2004 be changed to ISO/IEC 17065:2012;

Comment #12: Line 394 – Editorial revision is suggested: "Generally used when the risks associated with the object of assessments non-conformity" revised to ""Generally used when the risks associated with the object of **assessment's** non-conformity";

Comment #13: Line 488 – We recommend that you add reference materials and proficiency testing to the following sentence 'Accreditation activities include tasks such as testing, calibration, inspection, **reference materials, proficiency testing**, certification, management systems, …';

Comment #14: Line 488 – Accrediting bodies assess tasks performed by conformity assessment bodies such as testing, calibration,…suggest revision to ensure clarity of the role of accreditation

bodies. “Accreditation activities include tasks such as” revised to “Accreditation activities include assessment of conformity assessment body testing, calibration,...”;

Comment #15: Line 491 – We recommend that you delete ‘and guides’ as all of the applicable ISO/IEC or ISO standards used in conformity assessment are all standards and no longer guides;

Comment #16: Line 499 – Figure 3 does not include reference to ISO/IEC 17024 certification bodies; however, section 3.4.2 is dedicated to the discussion of ISO/IEC 17024 personnel certification. Suggest revision to include reference to ISO/IEC 17024;

Comment #17: Line 503 – We suggest that somewhere within the ‘peer assessment’ vernacular the document should refer to or reference ILAC and IAF for clarification on which levels of peer assessment are deemed appropriate;

Comment #18: Line 506 – We recommend that you replace ‘assess and audit’ with ‘evaluate’;

Comment #19: Line 509-510 - Somewhere within the ‘International/Regional Cooperation’ vernacular the document should refer to or reference ILAC and IAF for clarification on which levels of peer assessment are deemed appropriate;

Comment #20: Line 646 – We recommend that you change ISO/IEC 17011:**2004** to ISO/IEC 17011:**2017**;

Comment #21: Line 652 – We recommend that you change reference from ISO/IEC 17021:2006 to ISO/IEC 17021-1:2015;

Comment #22: Line 655 – We recommend that you change ISO/IEC 17025:**2005** to ISO/IEC 17025:**2017**;

Comment #23: Line 663 – There is a duplicate entry on line 669.