

JOSEPH TRETLER, JR. VICE PRESIDENT, INTERNATIONAL POLICY

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November 25, 2015

Du Xiaoyan and Yu Lianchao China National Institute of Standardization No. 4 Zhi Chun Road, Beijing, China 100191

Dear Messrs. Du and Yu:

The American National Standards Institute (ANSI) would like to thank the Standardization Administration of China (SAC) and the Chinese National Institute for Standardization (CNIS) for the opportunity to comment on the draft national standard "Association Standardization – Part 1: Guidelines for Good Practice." ANSI has a long history of cooperation with China, and SAC and CNIS in particular. The Institute applauds this demonstration of transparency and request for feedback during an important transition period for China's standardization system.

By way of background, ANSI serves as the coordinator the U.S. voluntary consensus standards system. As coordinator, ANSI facilitates the public-private partnership that is at the core of the U.S. standards and conformance system, accredits standards developers and conformity assessment organizations, and represents the U.S. in various international fora, including ISO and IEC. The *ANSI Essential Requirements* govern the processes by which ANSI accredits standards developers and approves American National Standards. To date, more than 240 standards developers have been accredited by ANSI.

Since China's State Council published the plan for deepening the reform of China's standardization system in March 2015, ANSI has closely monitored and engaged its Chinese partners on the details of the rollout. Of the initiatives included in the plan, ANSI and its members are particularly interested in the promotion of association standards, a relatively new category of Chinese standards. During a recent trip to Beijing, ANSI shared a Chinese translation of the *ANSI Essential Requirements* with SAC as a demonstration of its commitment to cooperation on the issue.

ANSI is submitting its specific comments on the draft guidelines as an attachment to this letter that uses the provided template. In developing its comments, ANSI used the *Essential Requirements* document as the basis for its suggestions, and also solicited and considered comments from its membership. In addition to the specific comments provided, ANSI would like to emphasize the following three points:

 First, ANSI strongly recommends that Chinese associations developing standards be required to make participation in the standards development process open to all persons, including nonmembers, who are directly and materially affected by the activity in question;

- Second, ANSI recommends that associations be required to demonstrate transparency throughout the standards development process, including a required public notice and comment period during the initial and review periods;
- Third and finally, ANSI strongly suggests that SAC take steps to clarify key aspects of the guidelines and consider the question of compliance with this national standard. Though ANSI recognizes the voluntary nature of the guidelines, associations that do elect to follow them should clearly demonstrate that they have incorporated the guidelines into their process. Such compliance is only possible to the extent the core requirements are clear. For example, the ANSI Essential Requirements includes ANSI's definition of due process, which means that any person (organization, company, government agency, individual, etc.) with a direct and material interest has a right to participate by: a) expressing a position and its basis, b) having that position considered, and c) having the right to appeal. Due process allows for equity and fair play. The Essential Requirements document then establishes and defines the minimum acceptable due process requirements for the development of consensus for an American National Standard.

In closing, ANSI welcomes the opportunity to further discuss its comments at any point, and looks forward to continued engagement with China throughout the reform process.

Sincerely,

Joseph Tretler, Jr.

Vice President, International Policy

Association Standardisation - Part 1: Guidelines for Good Practice

Comments sheet

| Name | Phone optional | | Fax Optional | | E-mail | |
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| Organization | American National ganization Standards Institute | | address | 1899 L Street | NW, 11 th Floor, Wa USA | ashington, DC 20036 |
| Number of the Clause | Proposed change | | | R | ationale of your co | mments |
| 3.2 | Recommend adding a specific reference to the ISO definition of "standard", as contained in ISO Guide 2: 2004. | | | definitions for | TO have provided the term "standard woid confusion. | commonly accepted ", which should be |
| 4.1 | Modify text as follows: "Participation shall be open to all persons who are directly and materially affected by the activity in question." | | | openness to en persons directl in question car | ends strengthening sure, not just recony and materially af a participate. Please tirements article 1.1 | nmend, that all fected by the activity e see the <i>ANSI</i> |
| 4.2 | Recommend clarification. | | | language, espe extent that it m persons directl in question. For | ends clarifying the cially the term "propagate and restrict the particle and materially after reference, please direments article 1.1 | oportional" to the icipation of all fected by the activity see the ANSI |

| 4.3 | Add the following: "An association should also publish its work program publicly and should allow for a public comment period before adoption of each standard." | ANSI recommends strengthening the language in this section to require, not just recommend, transparency measures, which should apply to all participants. Please see the WTO Code of Good Practice, Provision J & L, and the ANSI Essential Requirements article 1.9 Written procedures. |
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| 4.4 | Modify text as follows: "properly address the objection of important stakeholders on- substantive issues," | ANSI notes that the use of such terms as "important" stakeholders, "substantial" issues, and "per procedure" should not limit the participation of any person directly and materially affected by the activity in question. Please see the <i>ANSI Essential Requirements</i> article 1.1 Openness. |
| 5.1.3.2 and 5.2.1 | Recommend clarification. | ANSI recommends the language included in these sections be strengthened to ensure, not just recommend, that associations compile and publish written procedures for developing standards. For reference, please see the <i>ANSI Essential Requirements</i> article 1.9 Written procedures. |
| 5.2.2 | Recommend clarification. | ANSI recommends that the written procedures of an association contain an identifiable, realistic, and readily available appeals mechanism for the impartial handling of procedural appeals regarding any action or inaction. Procedural appeals include whether a technical issue was afforded due process. For reference, please see the ANSI Essential Requirements article 1.8 and 2.8 Appeals. |

| 5.2.3 | Add the following text: "The association should afford a reciprocal opportunity for membership for related foreign and domestic standardization organizations." | ANSI recommends that in addition to seeking membership with relevant standardization organizations, Chinese associations should provide reciprocal membership and participation opportunities for outside standardization organizations. |
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| 5.3.1 | Recommend modification. | ANSI recommends that the phrase "involvement of association standards in patents" be replaced by text consistent with the concept of "essential patent claims". The Guidelines should also state that the association make every effort to implement concise rules relating to the inclusion of technology covered by essential patent claims. For reference, please see the ISO/IEC/ITU patent policy (http://www.itu.int/en/ITU-T/ipr/Pages/policy.aspx) and the ANSI Essential Requirements article 3.1 ANSI patent policy. |
| 6.1 | Modify text as follows: "The procedures offer association- members and all materially affected and interested stakeholders fair and effective access" | ANSI recommends that language included in this section on participation in the standards development process emphasize that the process is open to all materially affected and interested parties. For reference, please see the ANSI Essential Requirements article 1.1 Openness. |

| | | ANSI recommends that these sections clarify the need | |
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| 6.2.1 and 6.2.2 | | to publicly announce and seek comments on new | |
| | | proposed projects and revisions, beyond membership | |
| | Recommend clarification. | to include all materially affected and interested | |
| | | parties. For reference, please see the WTO Code of | |
| | | Good Practice Provisions J, L and N; and ANSI | |
| | | Essential Requirements article 1.5 and 2.5 | |
| | | Notification of standards development. | |
| | Replace the last two sentences with: | | |
| | "The association should provide | | |
| | public notification of an opportunity | ANSI recommends clarifying the need to seek public | |
| | to provide comments on draft | comments, not just comments from within the | |
| | standards, and should allow a | association's membership. For reference, please see | |
| | comment period for the submission | the WTO Code of Good Practice Provision J and ANSI | |
| 6.2.4 | of comments by any interested | Essential Requirements articles 1.1 and 2.1 Openness, | |
| | parties. The association should take | 1.5 and 2.5 Notification of standards development, as | |
| | into account, in the further processing | well as 1.6 and 2.6 Consideration of views and | |
| | of the standard, the comments | objections. | |
| | received during the period for | | |
| | commenting." | | |
| | Recommend adding text that includes | | |
| 6.2.5 | instructions and/or contact | | |
| | information for associations to | It is unclear from the text how associations will | |
| | | | |
| | publish at the national uniform | publish information about completed standards. | |
| | association standards information | | |
| | platform (<u>www.ttbz.org.cn</u>). | | |
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| 6.2.5 | Recommend clarification. | ANSI recommends clarifying the relationship or difference between "voting" and "consensus" in approving a standard. For reference, please see <i>ANSI Essential Requirements</i> article 1.7 Consensus vote, 2.7 Evidence of consensus and Consensus body vote and ANSI's definition of consensus in Annex A. |
| 6.2.6 | Recommend including additional details in this section on the process by which a standard is maintained. | For reference, please see <i>ANSI Essential Requirements</i> article 4.7 Maintenance of American National Standards. |
| 7.1 | Recommend replacing text with: "Where international standards exist or their completion is imminent, the standardizing body should use them, or the relevant parts of them, as a basis for the standards it develops, except where such international standards or relevant parts would be ineffective or inappropriate." | ANSI recommends including a preference for international standards where they exist and are appropriate, as included in the WTO TBT Agreement. |
| 7.4 | Recommend clarification. | ANSI recommends clarifying the intent of this article, including the extent to which one type of association standard is preferred over another, and the connection to conformity assessment. |

Recommend deleting the second paragraph:

"When appropriate, the association should try to set up a unified certification system based on its standards, and develop a series of certification system documents and certification specifications such as certification modes, certification procedures and certification marks. Participation of certification bodies is encouraged during the development."

ANSI recommends that any discussion of establishing a uniform certification system based on association standards consider the need to separate the definition of standards requirements from conformity assessment methods for determining the fulfillment of those requirements as required by ISO's neutrality principle and defined in accordance with ISO CASCO standards.

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