



Standards Alliance Quarterly Report 2018 – Q2

Period of Performance:

April 1 – June 30, 2018

INTRODUCTION

The following report contains a summary of the major activities completed and outcomes achieved of the Standards Alliance, a public-private partnership between the American National Standards Institute (ANSI) and the U.S. Agency for International Development (USAID). The enclosed report contains a summary of all activities completed in the second quarter of 2018.

The <u>Standards Alliance</u> was announced by USAID in November 2012 as a new funding facility designed to provide capacity building assistance to developing countries, specifically related to implementation of the WTO Technical Barriers to Trade (TBT) Agreement. In May 2013, USAID and ANSI entered into a public-private partnership, which will coordinate subject matter experts from throughout the private sector-led U.S. standardization system in the delivery of training and other technical assistance to interested Standards Alliance countries.

SUMMARY OF ACTIVITIES COMPLETED DURING PERIOD OF PERFORMANCE

This period of performance was dedicated primarily to implementation of activities described in the country-specific work plans in Mozambique, Latin America, and West Africa; as well as planning for third quarter 2018 activities. A general summary of these activities, according to their country or region is listed below.

General Program Management/Promotion

• Outreach to engage partner agencies, organizations, and countries

ANSI updated the Standards Alliance website including the dates and locations of project activities and trainings conducted in partnership with other agencies and organizations, as well as materials from past events. Also, through regular email correspondence, ANSI updated its members and U.S. government stakeholders.

Colombia, Mexico, Peru and CAFTA-DR

 Advanced Medical Technology Association (AdvaMed) Regulatory Coherence, Good Regulatory Practices and Capacity Building Project in Latin America- Virtual Training (Year 5 Annual Plan #1, updated in Q1)

As part of its final deliverable, AdvaMed has been working with its subcontractor Venable to record training videos for a virtual training session which will take place during Q3

2018. The training videos will be posted online for use by Latin American medical device regulators, authorities and industry. Presentations will include content related to Tier 1 of the Standards Alliance initiative – Good Regulatory Practices, and (Tier 2) medical device technical regulations, standards, conformity assessment. AdvaMed also plans to include a dedicated Tier 3 presentation focused on international standardization, in which AAMI and ASTM will present for the global community.

The video presentations will focus on Tier 1, 2 and 3 results, including the GRP gap analyses conducted in Colombia, Costa Rica, Mexico and Peru. The presentations will also provide an overview of international reference documents available for medical device regulators and industry; and offer comparative analysis and suggestions for future work.

Mozambique

• Workshop on Good Regulatory Practices (GRP) (Year 5 Annual Plan #11)

The Standards Alliance in collaboration with USAID's SPEED+ project, Instituto Nacional de Normalização e Qualidade (INNOQ) and the government of Mozambique organized a two-day workshop in Maputo, Mozambique on May 21-22, to promote the implementation of Good Regulatory Practices (GRP) and to commemorate World Metrology Day.

The workshop featured presentations from SPEED+, the Office of the U.S. Trade Representative (USTR), ASTM International, the American Concrete Institute (ACI), and the Standards Accreditation and Trade Advisors (SAT). Representatives from INNOQ, the Ministry of Commerce and Industry, the National Institute of Transportation (INATTER), and Mozambique Engineering Laboratory (LEM) also shared perspectives from Mozambique.

U.S. government and private-sector speakers presented to over 70 participants and discussed metrology, application of good regulatory practices, regulatory cooperation, development of technical regulations, regulatory impact assessment, the use of standards and conformity assessment, stakeholder engagement, and integrating government and private sector perspectives. Workshop participants engaged in an interactive breakout Q&A session, which focused on strategies for improving national quality and good regulatory practices in Mozambique.

Workshop attendees expressed an interest in follow-up workshops on intragovernmental communication to support transparency and WTO notification processes in Mozambique.

• West Africa Risk-Based Consumer Protection Workshop Series (Year 5 Annual Plan #21)

On June 25-29, the Standards Alliances hosted a three-part workshop series covering best practices and risk-based approaches for consumer protection in Cote d'Ivoire, Ghana, and Senegal. The workshop series was a follow-up to the West Africa Delegation visit which took place in Washington, DC in October 2017.

The three-part workshop provided an opportunity to share perspectives and experiences on the U.S. consumer protection system and to support trade-friendly consumer protection laws and policies with the participating West African economies. More than 150 participants attended the events, which featured presentations from ASTM International, DeyTec, Personal Care Product Council (PCPC), Underwriters Laboratory (UL), the National Institute of Standards and Technology (NIST), and the International Trade Administration (ITA). Representatives from each participating country provided an overview of their national consumer protection strategies and difficulties.

The roadshow began on June 25 in Accra, Ghana, and was co-hosted by the Ghana Standards Authority (GSA). The day-one workshop was attended by 42 participants and featured presentations by ASTM International, DeyTec, PCPC, UL, NIST, ITA, and the Ghanaian Ministry of Trade and Industry (MOTI). Standards Alliance participants traveled to Abidjan, Cote d'Ivoire, for a workshop co-hosted by Côte d'Ivoire Normalisation (CODINOR) on June 27. This event was attended by 65 participants and included presentations by ASTM International, DeyTec, PCPC, UL, NIST, ITA, and the Ivorian Ministry of Commerce.

The roadshow concluded in Dakar, Senegal, on June 29, with a workshop co-hosted by the Senegalese Ministry of Commerce and the Association Senegalaise de Normalisation (ASN). This third workshop was attended by 49 participants and included presentations by ASTM International, DeyTec, PCPC, UL, NIST, ITA, the Senegalese Direction du Commerce Interieur (DCI), and ASN.

 Planning for the West Africa National Enquiry Point/National Notification Authority Trainings with Diane Thompson (New addition to Year 6 Annual Plan)

ANSI and ASSESS worked to finalize a contract with Diane Thompson to provide one follow-up training with the National Enquiry Points/National Notification Authorities in Ghana, Cote d'Ivoire, and Senegal. ANSI is currently working with representatives from GSA, CODINORM, and ASN to confirm the dates for this training series, which is expected to occur in October 2018.

Southern Africa

Standards Alliance Participation at the ARSO General Assembly (New addition to the Year 5 Annual Plan)

On June 18-22, 2018, the Standards Alliance participated in the African Organization for Standardization (ARSO) General Assembly which was hosted by the South African Bureau of Standards (SABS) in Durban, South Africa. The opportunity for the Standards Alliance to participate arose following discussions between ANSI and ARSO under their Memorandum of Understanding signed in 2014. The focus of the ARSO General Assembly aligned with priorities already identified in the work plans with Standards Alliance partner countries in Africa, and the opportunity was deemed worthwhile by ANSI and USAID.

U.S. speakers shared their perspectives on the importance of standards in international development and as a mechanism to augment regional trade. U.S. speakers included representatives from ASTM International, Underwriters Laboratories (UL), and the U.S. Foreign Commercial Service (FCS), who presented alongside representatives from the International Organization for Standardization (ISO), the United Nations Development Programme (UNDP), and Physikalisch-Technicsche Bundesanstalt (PTB).

The five day meeting included a roundtable discussion on the "Strategies for ARSO Sustainability within the Strategic Plan 2017 – 2022", a lecture by the Secretary-General on the "Role of Quality Infrastructure and Standardisation in facilitating Trade and Sustainable Development within the African Continental Free Trade Area (CFTA)" and discussions on "ARSO Fund mobilization with Sudan private sector players for the implementation of the Strategic Plan 2017-2022 within the Continental Free Trade Area (CFTA)."

<u>Zambia</u>

Planning for the Training on Regulatory Impact Assessment 1.5 (Year 5 Annual Plan #14)

ANSI has been coordinating with the Business Regulatory Review Agency (BRRA) of Zambia to outline the structure and logistics for a July training for Zambian regulators to better understand and perform regulatory impact assessments. ANSI is also working with a consultant, Nathan Frey (formerly from OMB-OIRA), to develop workshop materials.

Planning for Workshop on Liquid Cooking Fuels (Year 5 Annual Plan #10)

ANSI is working with the Zambia Bureau of Standards (ZABS) and POET to organize a workshop on liquid cooking fuels in early November 2018.

#	Country	Definition	Required in Work Plan?
1.	United States	Provided regular project updates and communication to government and private sector stakeholder groups outlined in the project plan	Yes
2.	United States	Posted project news and activities to the Standards Alliance website	Yes
3.	Colombia, Mexico, Peru and CAFTA-DR	Advanced Medical Technology Association (AdvaMed) Virtual Training	Yes
4.	West Africa	Risk-Based Consumer Protection Follow-up Roadshow	Yes
5.	West Africa	National Enquiry Point/National Notification Authority Trainings	No
6.	Mozambique	Workshop on Good Regulatory Practices	Yes
7.	Zambia	Technical Training on Regulatory Impact Assessment	Yes
8.	Zambia	Workshop on Liquid Cooking Fuels	Yes
9.	Southern, East, and West Africa	U.S. presentation and panel participation at the ARSO General Assembly	No

The primary outcomes for the period of performance are outlined in the table below.

This period of performance included a combination of execution and planning for future activities some of which will take place in the third and fourth quarter of 2018. The outcomes witnessed in Q2 are positive and represent the continued success of the Standards Alliance program.

In particular, activities carried out during the ARSO GA built on ANSI's MOU commitments to bolster cooperation between the two organizations in connection with existing and new initiatives. Presentations for U.S. private sector representatives helped elevate the Standards Alliance platform as a resource for capacity building on eliminating trade barriers and strengthening standards development, and conformity assessment, as the continent embarks on the newly established African Continental Free Trade Area (CFTA).

Importantly, this quarter also represented the conclusion of activities funded by the original Standards Alliance agreement with USAID. While the virtual training videos prepared by AdvaMed will be completed in Q3, all significant effort and federal funding has been fulfilled. Programming in 5 countries in Africa will continue until 2021, and ANSI's annual report will contain further evaluation and reflection on the first 5 years of the Standards Alliance.

CONCLUSION

This period of performance achieved important milestones for the Standards Alliance such as the conclusion of AdvaMed's work plan with medical device regulators in Latin America and the implementation of key workshops in Mozambique and West Africa. The Standards Alliance also witnessed significant progress toward completion of the year five activities. ANSI looks forward to building off these successes in the next period and carrying out activities with Ghana, Cote d'Ivoire, Senegal, Zambia and other partners.