



Period of Performance: October 1 – December 31, 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 third quarter of 2018.

The [Standards Alliance](#) 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. In September 2016, the ANSI-USAID agreement was extended to five additional countries and the period of performance extended until September 2021.

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 Latin America, Mozambique, and Zambia; as well as planning for 2019 activities in West Africa. 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 2018)*

AdvaMed and Venable completed recording training videos for a virtual training session which is scheduled to take place in Q1 2019, and which will complete this work plan activity. 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.

West Africa (Cote D'Ivoire, Ghana, and Senegal)

- *West Africa National Enquiry Point/National Notification Authority Trainings with Diane Thompson (Year 6 Annual Plan #14)*

During the week of October 15, 2018, the Standards Alliance in coordination with Côte d'Ivoire Normalization (CODINORM), Ghana Standards Authority (GSA), and the Senegalese Standards Association (ASN) organized three targeted training sessions in West Africa. The workshops, titled “Improving the World Trade Organization (WTO) Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Enquiry Points and Notification Authority,” took place in Cote d'Ivoire, Ghana, and Senegal and focused on providing practical training to National Enquiry Point (NEP) and National Notification Authority (NNA) staff.

52 total participants from Cote d'Ivoire, Ghana, and Senegal attended the training sessions, which were led by Thompson Consulting, LLC. The trainings built upon previous work under the Standards Alliance, aimed at supporting effective procedures and notification practices in line with the WTO TBT and SPS agreements. The sessions also provided guidance on procedural components of NEP/NNA operations, which help support each nation in fulfilling its obligations under the WTO agreement and to improve the efficacy of their respective NEPs and NNAs. Topics covered include: responding to inquiries, issuing notifications, handling and responding to comments, and written operating procedures, among other items.

- *Planning for West Africa Good Regulatory Practice (GRP) Workshop Series in Cote d'Ivoire, Ghana, and Senegal (Year 6 Annual Plan #1, 3 & 8)*

In follow-up to the Three-part, West Africa Consumer Protection Workshop Series, which took place in June 2018, the Standards Alliance in close collaboration with ASN, CODINORM, DCI, and GSA has been working to organize another workshop series on good regulatory practices. ANSI and the aforementioned national standards bodies are currently developing a timeline and general program for this activity, which is tentatively planned for Q2 2019.

- *Planning for Standards-Specific Workshop in Senegal and Ghana (Year 6 Annual Plan #4 & 9)*

The Standards Alliance has been coordinating with GSA, DCI, and ASN to refine workshop topics and timelines for standards specific workshops in Ghana and Senegal. These workshops are tentatively planned for Q2 or Q3 2019.

- *Planning for Cote d'Ivoire ISO 37001 and 37101 workshops (Year 6 Annual Plan #2)*

The Standards Alliance and CODINORM have been discussing the possibility of two sensitization workshops on ISO standards for sustainable development (37101) and anti-corruption (37001). These events are intended to build on Cote d'Ivoire's goals for developing better community management systems in 2019. ANSI has been working with relevant U.S. standards bodies to develop a timeline for this activity, which is tentatively planned for Q2 2019.

Mozambique

- *Workshop on Standards and Conformity Assessment: Tools to Facilitate Trade and Market Access (Year 5 Annual Plan #15)*

On December 3-4, 2018, the Standards Alliance in coordination with INNOQ and SPEED+ organized a two-day workshop in Maputo, Mozambique to promote best practices in the development of standards and conformity assessment systems. The workshop provided an opportunity for Mozambican and the U.S. experts to exchange information and increase their understanding of various aspects of standards, metrology, conformity assessment, as well as general good regulatory practices.

More than 100 participants attended the workshop, which featured presentations from five U.S. organizations and nine Mozambican organizations from the public and private sectors. Presentations focused on various components of national quality infrastructure including technical barriers to trade, best practices for standards and regulatory development, interagency coordination, stakeholder engagement, public consultation, and transparency. Following the roundtable event, the government of Mozambique, INNOQ, and SPEED+ agreed to find proactive ways to reconvene Mozambique's TBT

Committee and to ensure better communication across relevant government entities related to TBT issues.

Zambia

- *Workshop on Liquid Cooking Fuels (Year 5 Annual Plan #10)*

The Standards Alliance in collaboration with the Zambia Bureau of Standards (ZABS) and POET organized a one-day workshop on liquid cooking fuel standards in Lusaka, Zambia on November 1, 2018. The event was a replica of the Standards Alliance Workshop on Ethanol Cooking Fuel Standards, which took place in Uganda during the fall of 2016 and led to the adoption of ASTM International's standards for ethanol as a home cooking and appliance fuel, which were approved as Ugandan national standards. The one day workshop enabled a technical exchange on a variety of international standards, including the [ASTM International](#) standard for ethanol as a home cooking and appliance fuel.

The workshop highlighted a variety of liquid cooking and home appliance fuels, including ethanol and featured presentations from U.S. and Zambian experts. Presentations from ZABS and the Zambian Ministry of Energy underscored the value of cooking fuel standards and renewable energy goals and programs that exist in Zambia. U.S. presenters from POET, Project Gaia, and Dalberg provided information on standards for ethanol as a cooking fuel, liquid cooking fuel programs across Africa, practical cooking fuels standards, and methods for scaling cooking fuels in Africa. The event also included discussions on ASTM E3050, Standard Specification For Denatured Ethanol for Use as a Cooking and Appliance Fuel for denatured ethanol for use as a clean cooking fuel and appliance and Uganda's experience with this standard following a 2016 Standards Alliance activity.

- *Planning for In-Depth Regulatory Impact Assessment Training (Year 6 Annual Plan #13)*

The Standards Alliance and the Business Regulatory Review Agency (BRR) have been developing a four- to five-day training program intended to educate 30 Zambian regulators to perform better and train their colleagues to perform quantitative and qualitative analysis for regulatory impact assessments. The event is currently being planned for April 2019, and ANSI is working to coordinate with relevant U.S. public and private sector experts to support this training.

EVALUATION OF ACTIVITIES

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

#	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	National Enquiry Point/National Notification Authority Trainings	Yes
5.	Mozambique	Workshop on Standards and Conformity Assessment: Tools to Facilitate Trade and Market Access	Yes
6.	Zambia	Technical Training on Regulatory Impact Assessment	Yes
7.	Zambia	Workshop on Liquid Cooking Fuels	Yes

This period of performance included a combination of execution and planning for future activities in the first and second quarter of 2019. The outcomes witnessed in Q4 are positive and represent the continued success of the Standards Alliance program.

In particular, the Workshop on Liquid Cooking Fuels in Zambia demonstrated the program's ability to replicate past successes in other countries seeking similar cooking fuel solutions. In addition, the culmination of the Regulatory Coherence and Good Regulatory Practices project for medical device regulators is an important milestone that will result in a baseline against which U.S. industry can measure improvements in the regulatory systems of their target markets in Latin America. The set of training videos will be available as a resource to staff of the relevant ministries as they change positions, and will serve as a tool for U.S. stakeholders in their outreach.

CONCLUSION

This period of performance achieved important milestones for the Standards Alliance such as the implementation of key workshops in Zambia and West Africa. ANSI looks forward to building off these successes in the next period and carrying out activities with Ghana, Cote d'Ivoire, Senegal, Mozambique, Zambia, and other partners.