



Period of Performance: July 1 – September 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 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 Mozambique, Latin America, and Zambia; as well as planning for fourth 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 before the end of the year. 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)

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

ANSI, ASSESS, and Diane Thompson worked to finalize agendas for trainings with the National Enquiry Points/National Notification Authorities in Ghana, Cote d'Ivoire, and Senegal. This activity is scheduled to occur as one-day trainings during the week of October 15, 2018 in each participating country.

Mozambique

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

The Standards Alliance, SPEED+, and INNOQ have been working in close collaboration to organize a workshop on standards and conformity assessment to align with the release of the SPEED+-developed handbook on Standards, Metrology, and Conformity Assessment. After agreeing to a draft concept for this activity, this event has been tentatively planned for December, 2018.

Zambia

- *Training on Regulatory Impact Assessment 1.5 (Year 5 Annual Plan #14)*

The Standards Alliance organized a two-day training in Lusaka, Zambia on July 19-20 titled "Evidence-based Regulatory Decision Making: the role of RIA and Public Consultation." This workshop was co-hosted by Zambia's Business Regulatory Review Agency (BRRRA), and was held in follow up to an April 2017 training on RIA soon after the establishment of BRRRA as an agency. The July training focused on increasing use of Regulatory Impact Analysis (RIA) in the Zambian regulatory system and providing practical training for Zambian regulators on RIA implementation.

The training included 28 Zambian regulators and 5 members of BRRRA. The event featured presentations by U.S. and Zambian participants including presentations from Grocery Manufacturer's Association (GMA), National Commission for the Certification of Crane Operators (NCCCO), Regulatory Strategies and Solutions Group (RSS Group), the International Air Transport Association (IATA), BRRRA, the Zambian National Water Supply and Sanitation Council, Zambian Water Resources Management Authority, Zambian National Broadcasting Corporation, and Zambia Railways Limited.

The two-day training included an evening ceremony promoting the release of the Zambian "RIA Handbook" and the "RIA Standards and Guidelines" by Permanent Secretary Kayula Siame. The handbook and guidelines describe the legal underpinnings and detail the processes and procedures for RIA in Zambia.

- *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 on November 1, 2018. This activity will mirror previous Standards Alliance workshops in Uganda that paved the way for the national adoption of the ASTM ethanol cooking fuel standard, ASTM E3050.

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 some of which will take place in the third and fourth quarter of 2018. The outcomes witnessed in Q3 are positive and represent the continued success of the Standards Alliance program.

In particular, the training on regulatory impact assessment (RIA) in Zambia demonstrated an important continuation of previous efforts to build upon basic elements of RIA to more advanced aspects of implementation. This progression has been met with high interest from the Zambian Ministry of Commerce and Business Regulatory Review Agency, which have requested that additional training for Zambian regulators and "train the trainer" activities be included in the Standards Alliance year 6 work plan.

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. The Standards Alliance also witnessed initiation of year six activities and a shift toward exclusive programming in 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.