



Period of Performance: January 1 – March 31, 2017

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 first quarter of 2017.

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.

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 Indonesia and Vietnam; as well as the finalization of the Trade Africa expansion and the coordination of the associated country work plans. 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. This also included the addition of a West Africa page reflecting the Trade Africa expansion. Also through regular email correspondence, ANSI updated its members and U.S. government stakeholders.

Indonesia

- *Workshop on Key Aspects of Good Regulatory Practice: Tools to Effectively Achieve Policy Goals-* (New addition to Year 4 Annual Plan)

On March 15-16, 2017, the Standards Alliance in collaboration with the U.S. Embassy in Jakarta and the Indonesian Ministry of Trade (MOT) held a 2-day workshop entitled “Key Aspects of Good Regulatory Practice (GRP): Tools to Effectively Achieve Policy Goals ” in Jakarta, Indonesia. The workshop originated during a recent government-to-government meeting in which the MOT requested further training from the U.S. on the subject of good regulatory practice, in support of goals outlined in platforms such as the U.S.-Indonesia Trade and Investment Framework (TIFA).

More than 150 participants representing Indonesian public and private sector organizations attended the workshop. Speakers from the U.S. represented the Office of the United States Trade Representative (USTR), Office of Management and Budget Office of Information and Regulatory Affairs (OMB-OIRA), ASTM International, International Association of Plumbing and Mechanical Officials (IAPMO), International Code Council (ICC), and Shell Corporation. Speakers from Indonesia also included a mix of public and private sector organizations such as MOT, Ministry of Law and Human Rights (MOLHR), Employers Association of Indonesia (APINDO), Ministry of Home Affairs, Center of Strategic and International Studies (CSIS), Atma Jaya University, American Chamber of Commerce, Indonesia and the U.S.-ASEAN Business Council.

MENA (Jordan)

- *Planning for U.S.-Gulf Conference on Good Regulatory Practice and Regulatory Impact Assessment -* (Year 4 Annual Plan #10)

The Standards Alliance, in partnership with USTR, the Gulf Cooperation Council (GCC) and Gulf Standards Organization (GSO) worked together to finalize an agenda and to solidify private and public sector speakers for a 3-day workshop on good regulatory practices, regulatory impact assessment, and implementation of the WTO Technical Barriers to Trade (TBT) Agreement.

The idea for the workshop came at the suggestion of the Secretary General of GSO, Nabil Molla, during meetings in the U.S. last year. The proposal was to hold a joint workshop to discuss GRP and TBT-related issues and to provide an opportunity for U.S.-GSO exchange. The workshop is set to take place on April 24-26, 2017 in Riyadh, Saudi Arabia. The request matched priorities set by the Jordan Standards and Metrology Organization (JSMO) as part of Standards Alliance work planning, so ANSI was able to invite two officials from JSMO in the Riyadh workshop and maximize impact in the region. The U.S. delegation will include 3 government speakers from USTR, EPA and OMB-OIRA and 5 private sector speakers from ASTM International, Intertek, Red Wing Shoe, American Chemical Council and Proctor and Gamble.

- *Improving regulatory framework related to water and sanitation (IAPMO)- (New Addition to Year 4 Annual Plan)*

The Middle East and North Africa Region (MENA) is the most water scarce area in the world. As such, water and sanitation systems in this region face growing challenges, and international standards can play a fundamental role in establishing national strategies for addressing these issues as well as in meeting governmental commitments under the WTO's Technical Barriers to Trade agreement. Under this project, IAPMO has partnered with stakeholders in the country of Jordan to improve their regulatory framework related to water and sanitation services as well as address workforce development issues and supply chain mechanisms.

IAPMO staff met with officials from the Jordan Standards and Metrology Organization (JSMO), the Ministry of Public Works and Housing (MPWH), the Jordanian Royal Scientific Society (RSS), and the Water Authority of Jordan in Amman, Jordan. Each one of these government organizations and officials play a key role in updating the plumbing code, establishing a certification scheme, and personnel certification requirements. Following up from previous quarter's efforts, MPWH has formally requested RSS to submit a proposal to update the plumbing code. The initial proposal had been developed and returned to MPWH. An MOU has been tentatively approved by IAPMO and JSMO. It is currently circulating with the MPWH and WAJ for their approvals.

IAPMO staff also met with the Arab Countries Water Utilities Association (ACWUA). ACWUA has been leading in Jordan and in the region in creating water-related personnel training programs. IAPMO presented on the Standards Alliance and the project at ARAB Water Week 2017. This attracted the interest and potential support of several new stakeholders. IAPMO co-presented with the staff from the Centre for Accreditation and Quality Assurance (CAQA) under the Ministry of Labor. CAQA has the primary responsibility for establishing the personnel certification requirements and accrediting training organizations.

Peru

- *Peru Workshop on Medical Device Regulation and Standards Phase II: Policy and Technical Aspects - (Year 4 Annual Plan #11)*

On January 24-25, 2017, the Standards Alliance hosted a two-day workshop on medical devices in collaboration with Instituto Nacional de Calidad (INACAL) and ASTM International. The workshop focused on components of Good Regulatory Practice (GRP) in Healthcare, Medical Device Standards in Regulations, Technical Trainings on Various Material Test Methods and the ASTM standardization process. The workshop was attended by over 55 Peruvian participants from both the public and private sector. Representatives from the Food and Drug Administration (FDA), the American Dental Association (ADA), Boston Scientific, ASTM International, Empirical Technologies,

Cambridge Polymer Group, and ANSI shared the U.S. perspective. The Peruvian viewpoint was represented and shared by officials from the National Institute of Quality (INACAL), Medicines, Supplies and Drugs (DIGEMID), Ministry of Foreign Trade and Tourism (MINCETUR), National Institute of Health (INS), and Perú Compras.

Participants actively participated throughout the workshop and pointed out the difficulties in medical device quality control, given the diversity of tests and the lack of uniform standards for similar products. Participants from both the private and public sector were particularly interested in engaging FDA and asked several questions about FDA's role and U.S. regulations. FDA was instrumental in highlighting that the U.S. uses a level of risk classification system to guarantee the safety and efficiency of medical devices currently in the U.S. market.

Colombia, Mexico, Peru and CAFTA-DR

- *Advanced Medical Technology Association (AdvaMed) Regulatory Coherence, Good Regulatory Practices and Capacity Building Project in Latin America- (New addition to Year 4 Annual Plan)*

At the end of 2016, AdvaMed submitted a proposal for a project promoting the use of good regulatory practices for the medical devices sector, with a focus on the Standards Alliance partner countries in Latin America. The project includes both horizontal activities aimed at good regulatory practices broadly, as well as sector-specific activities for the medical device sector.

The first quarter of 2017 has been very productive with the majority of AdvaMed's focus going into creating formalized guides and establishing connections for future activities. The following activities were carried out:

- AdvaMed completed the landscaping of international Regulatory Coherence benchmarks and compiled the Regulatory Coherence (Good Regulatory Design) Policy Guide. The Guide, which was completed in English is currently being translated into Spanish and will serve as the core deliverable of Tier 1, Phase 1. This document will also include the benchmark for the Regulatory Coherence gap analyses.
- Under Tier 2 Phase 1: The landscaping of key Medical Device specific Good Regulatory Practices (GRPs), Model Frameworks, and Standards was initiated and is currently underway. Four core documents have been identified:
 - World Health Organization Quality Assessment System (WHO QAS)/16.686/Draft for comment: Good Regulatory Practices: Guidelines for National Regulatory Authorities for Medical Products [Draft – October 2016]

- WHO QAS/16.664/Rev.2: WHO Global Model Regulatory Framework for Medical Devices Including In Vitro Diagnostic (IVD) Medical Devices [Revised Draft – September 2016]
 - ISO 16142-1 International Standard: Medical Devices – Recognized Essential Principles of Safety and Performance of Medical Devices – Part 1: General Essential Principles and Additional Specific Essential Principles for all non-IVD Medical Devices and Guidance on the Selection of Standards [First Edition 2016-03-01]
 - ISO 16142-2 FDIS: Medical Devices - Recognized Essential Principles of Safety and Performance of Medical Devices – Part 2: General Essential Principles and Additional Specific Essential Principles for all IVD Medical Devices and Guidance on the Selection of Standards [Final Draft International Standard 2016-03-01]
- The Medical Technology Associations in Colombia, Mexico, Peru were contacted and expressed their preparation and support of the initiative Asociación Nacional de Empresarios de Colombia – Camera de Dispositivos Médicos (ANDI-CDMIS), Asociación Mexicana de Industrias Innovadora de Dispositivos Médicos (AMID), Cámara de Comercio de Lima - Gremio de Salud (CCL-COMSALUD) in their respective countries, working with their respective regulatory committees and governments.
 - The Regional Medical Technology Associations were contacted and expressed their preparation and support of the initiative (Latin American Medical Technology Association (ALDIMED) and Latin American Medical Technology Association (ALADDIV)).
 - ALDIMED and ALADDIV began negotiating a joint MOU to work together on regional regulatory matters with the Standards Alliance being a driving factor.
 - AdvaMed contracted ALADDIV to serve as regional technical coordinator for the project.
 - AdvaMed contracted the Global Regulatory Cooperation Center and the George Washington University Regulatory Studies Center to drive the development of the Regulatory Coherence Guide.
 - AdvaMed and ALADDIV participated in the International Medical Device Regulators Forum (IMDRF) meeting March 12-16, 2017 in Vancouver, Canada and secured the support of the WHO and the Pan American Health Organization (PAHO) for the Standards Alliance project.
 - Initial planning is underway for GRP and Standards Workshops as follows:

- Ottawa – Canada: September 21-22, 2017 (in conjunction with IMDRF)
 - San Francisco, CA – USA: February, 2018 (in conjunction with APEC RHSC – LSIF)
- Other regulator events tentatively being considered include:
- Washington, DC – USA: Q3-Q4, 2017 (in conjunction with the Pan American Health Organization (PAHO) and/or FDA, OMB, ITA)
 - China: March 2018 (in conjunction with IMDRF)

AdvaMed plans to complete Tier 2 Phase 1: Implementation Guide in the next quarter. Tier 1 and Tier 2, Phase 2 are scheduled to beginning in May 2017 and Tier 1 & 2 of Phase 3 and 5 are scheduled to begin by Q4, 2017.

Southern African Development Community (SADC)

- *Focused TBT NNA/NEP training for Mozambique by Thompson Consulting (Year 4 Annual Plan #13)*

In March, Diane Thompson of Thompson Consulting, worked with the TBT Enquiry Point/ Notification Authority staff to develop a marketing plan to increase awareness of the Enquiry Point and promote its services. In addition, she provided on-site training in submitting notifications using the WTO TBT Notification Submission System.

- *Planning for training programs in Zambia and Mozambique on Good Regulatory Practices(Year 4 Annual Plan #14 and 17)*

In support of the first activities in ANSI's work plan for Zambia and Mozambique, ANSI worked with its partners ZABS and INNOQ, and the relevant USAID Missions to secure agreement on the dates and concepts for 2 training programs on elements of good regulatory practices.

In Zambia, the training will focus on regulatory impact assessment (RIA) and will also include participation from U.S. and Zambian industry groups and the newly established Zambia Business Regulatory Review Authority (BRRA). This training is scheduled to take place on April 24-25 in Lusaka, Zambia.

In Mozambique, the training will focus on public consultation and participation of the private sector in standards development and rulemaking. This training is proposed to take place in late June, 2017.

Vietnam/ASEAN

- *26th APEC Automotive Dialogue-* (New addition to Year 4 Annual Plan)

In collaboration with the Department of Commerce and NHTSA, the Standards Alliance plans to participate in the 26th APEC Automotive Dialogue (AD26) on May 10-12 and other bilateral meetings at the APEC General Assembly in Hanoi, Vietnam. The agenda for AD26 has been finalized.

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

- *West Africa Roadshow with for Cote d'Ivoire, Ghana, and Senegal* (Year 4 Annual Plan #21, 24, and 25)

On March 31 – April 5, 2017 the Standards Alliance hosted a three-part Standards Roadshow in West Africa. The roadshow featured one-day workshops in Cote d'Ivoire, Ghana, and Senegal. A group of U.S. private-sector speakers provided presentations on standards-related topics relevant to three key sectors: transportation infrastructure, water, and energy.

More than 140 participants attended the workshops collectively, which featured presentations by U.S. speakers from the American Water Works Association (AWWA), ASTM International, Deloitte, General Electric, and Western Transportation Institute (WTI), as well as the national standards bodies from each of the participating countries: Association Sénégalaise de Normalisation (ASN, Senegal), CODINORM (Cote d'Ivoire), and Ghana Standards Authority (GSA).

To broaden the reach of the event, ANSI partnered with the USAID-funded Analytical Support Services and Evaluations for Sustainable Systems (ASSESS) project to include a small number of participants from other West African countries. Regional participants included members of the national standards bodies from Benin, Guinea, Mali, Sudan, and Togo.

During the workshop series, ASTM International signed two Memorandums of Understanding (MoUs) with CODINORM and ASN. These agreements will grant CODINORM and ASN free access to more than 12,000 ASTM standards as well as access to technical experts to aid in the adoption of ASTM standards.

- *Focused TBT NNA/NEP training for Cote d'Ivoire, Ghana, and Senegal by Thompson Consulting* (Year 4 Annual Plan #20)

In January, Diane Thompson of Thompson Consulting, led trainings in Cote d'Ivoire, Ghana, and Senegal to improve the national TBT enquiry points and notification authorities. During the trainings Ms. Thompson provided technical assistance and on-

site training for the three countries. These workshops led to the development of Action Plans to improve the efficiency and effectiveness of each country's respective TBT enquiry points and notification authorities.

In March, Ms. Thompson returned to West Africa to help establish national TBT committees in Cote d'Ivoire, Ghana, and Senegal. These committees serve as an important forum for gathering public and private sector input on domestic and foreign technical regulations and other important TBT matters.

- *Preparation for Risk-based Consumer Protection Orientation Delegation visit by Senegal, Ghana, and Cote d'Ivoire (Year 4 Annual Plan #23)*

The Standards Alliance has worked with the national standards bodies of Cote d'Ivoire, Ghana, and Senegal to identify and invite 9 relevant participants from three Trade Africa countries plus 1 participant from Nigeria. Participating delegates from West Africa will spend 3 to 5 days touring U.S. organizations and government agencies to discuss risk-based consumer protection strategies used in the U.S. as well as international best practices.

The Standards Alliance is in the process of engaging U.S. organizations and government agencies to develop an agenda for the delegation visit, which is planned to take place in June/July, 2017.

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	Peru	Peru Medical Devices Workshop (Item 11)	Yes
4	SADC	NEP/NNA support through public-private stakeholder workshop (Item 13)	Yes
5	SADC	Planning for GRP training programs in Zambia and Mozambique (Items 14 and 17)	Yes
6	West Africa	West Africa Standards Roadshow (Items 21, 24, 25)	Yes
7	West Africa	Focused TBT NNA/NEP training for Cote d'Ivoire, Ghana, and Senegal (Item 20)	Yes
8	West Africa	Risk-based Consumer Protection Orientation Delegation visit by Senegal, Ghana, and Cote	Yes

		d'Ivoire (Item 23)	
9	Indonesia	Workshop on Key Aspects of Good Regulatory Practice: Tools to Effectively Achieve Policy Goals	No
10	Middle East/North Africa (Jordan)	Planning for U.S.-Gulf Conference on Good Regulatory Practice and Regulatory Impact Assessment (Item 10)	Yes
11	Vietnam-ASEAN	26th APEC Automotive Dialogue	No
12	Colombia, Mexico, Peru and CAFTA-DR	Advanced Medical Technology Association (AdvaMed) landscaping of international Regulatory Coherence benchmarks and completion of Regulatory Coherence (Good Regulatory Design) Policy Guide	No

This period of performance included a combination of execution and the planning of future activities, many of which will take place in Q2 and Q3 of 2017. The outcomes witnessed were positive and represent the continued success of the Standards Alliance.

In particular, activities carried out in West Africa proved to be extremely beneficial in opening dialogue, facilitating information sharing and fostering cooperation in West Africa. The West Africa Roadshow also resulted in the signing of two MoUs between ASTM International and the national standards bodies of Cote d'Ivoire and Senegal. GRP and TBT related activities in MENA and Indonesia built upon previous engagement on these issues and focused on advancing foundational best practices and specific regional priorities.

CONCLUSION

This period of performance achieved important milestones for the Standards Alliance such as the first series of workshops associated with the Trade Africa expansion and the coordination of future workshops with the five new Trade Africa countries: Cote d'Ivoire, Ghana, Mozambique, Senegal, and Zambia. Standards Alliance also witnessed significant progress toward completion of the 4th year's activities. ANSI looks forward to building off of these successes in the next period and carrying out activities with Vietnam, West Africa, Colombia, Mexico, Peru, CAFTA-DR and other partners.