

Period of Performance: January 1 – March 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 first 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.

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 and West Africa; as well as planning for second 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- (Year 5 Annual Plan #1)*

On January 15-19, the Standards Alliance hosted a Colombian delegation visit in the United States, examining Good Regulatory Practices for Tier 1 and Tier 2 regulatory issues in the medical devices sector. Tier 1 focused exclusively on identifying and validating

Colombia's horizontal GRP requirements across government agencies benchmarked against international best practice. Tier 2 focused exclusively on medical device regulations, standards and conformity assessment within the medical device sector.

On January 19, 2018, the Standards Alliance in partnership with AdvaMed held a 1-day workshop on Regulatory Convergence and International Standardization” at AdvaMed’s Washington, DC office. 11 representatives from the Colombian National Food and Drug Surveillance Institute (INVIMA), attended in-person meetings in New Jersey and Washington, including a roundtable meeting with AdvaMed and ANSI. The meeting aimed to review both the results to-date of the Standards Alliance project, as well as, to address select regulatory topics that could benefit from increased regulatory convergence.

More than 25 people representing U.S. public and private sector organizations attended the workshop. U.S. speakers represented the U.S. Food and Drug Administration (FDA), ANSI, AdvaMed, Johnson & Johnson, the Association for the Advancement of Medical Instrumentation (AAMI) and ASTM International. Speakers from Colombia included public sector participants from INVIMA. Presentations from Colombia provided an overview of Colombia's health standardization, medical device regulations, and INVIMA's experiences in premarket surveillance. Presentations also focused on topics in medical device regulation that can benefit from increased regulatory convergence and use of international standards.

The following outcomes were a result of the Colombian delegation visit:

- INVIMA was able to see firsthand the utility and advantages of health regulator mandates through the practical implementation of international standards and, conformity assessment and engagement in standardization.
- The Colombian Public Authority was able to benchmark its GRP policies and also gained insight on how those policies impact Colombian Medical Device Regulation and Standardization.
- Both INVIMA and the Public Authority have an increased appreciation for the USAID Standards Alliance initiative and mission, and the ongoing contributions that ANSI and the private sector can make to GRP and MD regulation and standardization.
- Following the week's meetings, INVIMA agreed to:
 - Formally continue its support of the Standards Alliance, and to hold such meetings with AdvaMed and ANSI annually to address regulatory areas that could benefit from increased international standardization.
 - Serve as a ‘multiplier organization’ incorporating and passing along the information in its capacity building with smaller regional medical device regulators.
 - Apply to become a member of the IMDRF.
 - Implement a GRP policy for the INVIMA Medical Device division.
 - Support efforts to implement a GRP policy for INVIMA as an agency and with the Ministry of Health.

Peru

- *Planning for ASME Advanced Manufacturing Workshop (Year 5 Annual Plan #6)*

The Standards Alliance and the American Society for Mechanical Engineers (ASME) are currently planning a two-day workshop designed to provide knowledge and tools required to participate in the advanced manufacturing industry. The workshop was set to take place in on April 11-12, 2018 but has been postponed to take place on June 12-13 in Lima.

Indonesia

- *IAPMO Water for Indonesia Now project – (Year 5 Annual Plan #3)*

IAPMO put together a demonstration project in Indonesia that achieved a major milestone in Q1 2018. The purpose of the project was to highlight the impact the new plumbing standard can have on community level construction projects as well as highlight the importance of training to the new standards. The project, known as the Community Plumbing Challenge 2017 (CPC2017), was conducted in Cicau Village, Bekasi, Indonesia. This demonstration project was structured similar to other projects that IAPMO has led in previous years, including in Diepsloot, South Africa (2016) and Nashik, India (2015).

For the CPC 2017, IAPMO brought together young, skilled experts, to develop creative solutions for designing and upgrading an existing toilet facilities in a Cicau school in collaboration with local community leadership. The project was delivered in three parts: a 'Design Week' in August 2017, 'Construction Week 1' in November 2017, and 'Construction Week 2' in March 2018. Plumbing, engineering and other general construction skill sets and products will be highlighted, with an emphasis on showcasing real life practices on how standardized plumbing systems and education can dramatically impact health and sanitation in public settings such as schools.

Before this project, SDN Cicau 02 had a total of four toilets, shared by approx. 300 students aged between seven and thirteen years old, and 12 staff. No handwashing facilities were present, and water supply to the school was pumped from a nearby, polluted lake. This project doubled the number of toilets, to eight (renovating the existing space) with improved drainage, light, ventilation, access and security. Two new handwashing areas were built (three taps each), designed at optimum height for the schoolchildren's use. Municipal water supply was reconnected, and two elevated 2000 liter water tanks were erected, designed to ensure reliable water supply to the school for at least two days at a time. Finally, a new wastewater system was installed: treating wastewater in a 3000ltr septic tank before draining to four Evapotranspiration Absorption ('ETA') beds at the back of the school grounds. The program presented a series of workshops including Maintenance Training at SDN Cicau, and an Introduction to new Indonesian Plumbing Standard SNI 8153:2015. Additionally, working in a school

environment allowed for ongoing classroom lessons and playground activities, including handwashing demos and promotion of World Plumbing Day, 2018. MOUs were signed with two Jakarta-based vocational schools, SMK 01 and SMK 26: teachers and students subsequently took part in all parts of the construction efforts.



The International Team included participants from Indonesia, Australia, India, Singapore and the U.S.A. The CPC program was presented with a Corporate Social Responsibility (CSR) award by the Government of Bekasi Regency, Regional Development Planning Agency, plus an official letter of endorsement and offer of facilitation for further initiatives in the region.

Additionally, IAPMO was also pleased to host program evaluators from USAID during Construction Week 2. In addition to providing them with an overview of the Standards Alliance project, arranging meeting with government officials, and showing them IAPMO's new laboratory in Indonesia, IAPMO was pleased to also have them participate in SDN Cicau 02 project. Pictures of their visit to the school are included below. Additionally, a more detailed summary of the CPC Indonesia project activity can be found [here](#).

Jordan – Middle East and North Africa (MENA)

- *IAPMO engagement with JSMO, MPWH, and RSS (Added to Year 5 Annual Plan in Q4 2017)*

At the end of Q4, IAPMO achieved an important milestone in its Standards Alliance project. IAPMO, in partnership with the Jordanian National Building Council (JNBC),

Water Authority of Jordan (WAJ), and Jordan Standards and Metrology Organization (JSMO) signed a memorandum of understanding (MOU) to enhance water/sanitation infrastructure in the kingdom through the continued development and enforcement of plumbing codes and standards. As part of this partnership, IAPMO has been working to coordinate its activities with the USAID-funded Water Management Initiative (WMI) Project. The purpose of this project is to advocate water use efficiency in Jordan to reduce non-beneficial water use which will most likely be offset by using the “saved” water for beneficial use. The program includes activities for water-use efficiency, improved conservation of freshwater and increased sale of treated wastewater to the private sector. In developing its project, WMI did extensive research and conducted meetings with relevant stakeholders also reviewing previous and existing WUE efforts in Jordan. The focus of these efforts was to get a better understanding of the current situation in Jordan, identify challenges and obstacles, and accordingly identify opportunities for implementing water-use efficiency in Jordan.

The research of WMI indicated that following are some challenges in terms of applying WUE in Jordan, and relate to IAPMO’s Standards Alliance efforts:

1. Insufficient enforcement of plumbing codes. The inspection process is usually as follows: The Jordan Engineers Association reviews the Design Drawings of proposed buildings for adherence to Jordanian Plumbing and Building Codes, in addition to other applicable laws. The building contractor is to hire an on-site engineer to assure all construction is following the Design Drawings. At no time does the jurisdiction enter the building to assure the plumbing meets the code requirements and the fixtures meet applicable product standards. The Greater Amman Municipality (GAM) only inspects for issues such as required offsets from property lines, before issuing an occupancy permit. There is no evidence that the plumbing system meets code requirements and the fixtures and fittings meet water efficiency standards.
2. Insufficient enforcement of product standards that allows water wasting products into Jordan. There is infrequent testing of water using devices for meeting water efficiency requirements. This leads to the presence of inefficient products in the Jordanian market, particularly among the lower-income clientele.
3. Products manufactured or assembled in Jordan are not subject to testing. Although it is estimated that most products are imported, this still allows potential for water wasting products to enter the Jordan market.
4. Water use labeling is non-existent for most plumbing products that are sold in the stores that target the lower-income clientele. There is no information printed on the product or the packaging to inform customers on water use. These customers usually choose products based only on price, style, features, and seldom inquire about water use or water efficiency.

5. There is no common label to signify products are water efficient compared to other similar devices, like WaterSense and Energy Star labels in the USA. The USAID research also noted the EU labels for clothes washers standards.
6. Toilet ceramics are imported (and sold to Jordanians) separate from the flush mechanism. This makes it impossible to test for water efficiency and guide customers in purchase decisions.
7. Water costs are subsidized to customers. While these subsidies are needed to provide social equity to the low-income customers, it also allows water waste to be subsidized. The full impact of using inefficient water devices is not borne by the consumer.

From this research, WMI recommended that the following measures be pursued by the water sector:

- Improve the enforcement and verification of plumbing codes and product standards. Perform on-site verification of water efficient products before issuing occupancy permit.
- Require water using products to mark the water flow or volume on the product. While it is true that small devices such as aerators allow for only small print, it is proven technically feasible. In addition, the package can have the same water use information and can be printed on packaging or an affixed label.
- Perform more water efficiency tests on imported products. Do not allow recalibration of products that fail the tests on the product standards; the factory setting should be used in all testing. Do not allow ceramics toilet tanks to enter country without flushing mechanisms installed. Test products manufactured or assembled in Jordan.
- Conduct WUE training and capacity building to designated staff at the water utilities and the Ministry of Water and Irrigation.

Additionally, IAPMO worked to continue to develop its specific plan of action to fulfill the cooperative framework laid out in December's MOU.

Mozambique

- *Planning for Workshop on Good Regulatory Practices (GRP) (Year 5 Annual Plan #11)*
During the first quarter, ANSI continued preparations for a GRP workshop in Mozambique in Q2 2018. This workshop is scheduled for May 21 and 22 in Maputo, Mozambique in coordination with World Metrology Day celebrations. ANSI is working with SPEED+, INNOQ, and the Government of Mozambique on final preparations for this event. ANSI is working with SPEED+ contractor, Ed Nemeroff, as well as Ileana Martinez to help strengthen workshop messaging and to develop presentations and interactive sessions for this event.

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

- *West Africa Training on Textiles and Apparel Standards: Ghana, Cote d'Ivoire, and Nigeria (Year 5 Annual Plan #23)*

The Standards Alliance collaboration with Ethical Apparel Africa (EAA), organized a two-part training series on textile and apparel standards in Ghana and Cote d'Ivoire in March. More than 100 people attended the two trainings, representing national standards bodies, testing labs, small and medium-sized textile/apparel manufacturers, designers, training and education facilities, ministries of trade and commerce, and sector-relevant associations. The participants learned about the U.S. standards system and the role of voluntary consensus standards in the U.S. apparel market.

Three U.S. technical experts from the American Association of Textile Chemists and Colorists (AATCC) and Bureau Veritas presented on standard testing methods for textile and apparel to support exports to the U.S. under the African Growth and Opportunity Act (AGOA), a preferential trade agreement between the U.S. and qualifying sub-Saharan African countries.

Additionally, local presentations were made by national standards bodies (the Ghana Standards Authority and CODINORM), USAID representatives and experts on AGOA, EAA, the Association of Ghana Industries (AGI), the Ghana Export Promotion Authority (GEPA), and an Ivorian textiles expert and representative to the Technical Committee on the Harmonization of African Standards.

- *Planning for the West Africa Risk-Based Consumer Protection Workshop Series (Year 5 Annual Plan #21)*

During quarter one, ANSI continued to work with the national standards bodies from Ghana, Cote d'Ivoire, and Senegal to develop the best strategy for a workshop series to follow up on the October Consumer Protection visit to the United States. ANSI is currently planning one-day events for high-level government and private sector participants in each of Ghana, Cote d'Ivoire, and Senegal during the week of June 25, 2018.

ANSI is coordinating with the U.S. government and private sector to develop a workshop agenda and presentations. Current speakers include representatives from the International Trade Administration (ITA), the National Institute for Standards and Technology (NIST), ASTM International, Underwriters Laboratory (UL), and DeyTec Inc.

- *Planning for the West Africa National Enquiry Point/National Notification Authority Trainings with Diane Thompson (New addition to Year 5 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 current working with representatives from Ghana Standards Authority (GSA), CODINORM, and the Association Senegalese de Normalization (ASN) to confirm the dates for this training series, which is expected to occur in the third quarter of 2018.

Southern Africa

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

In the first quarter of 2018, ANSI worked with the African Organization for Standardization (ARSO) to arrange U.S. participation at the 2018 ARSO General Assembly on June 18-22, 2018 in Durban, South Africa. At this time, ANSI, the U.S. Department of Commerce, and ARSO are working to finalize U.S. speakers for one 20 minute presentation and one, or more, speakers to participate in a panel covering "Sustainable development for African growth and the role of quality infrastructure activities."

Zambia

- *Standards in Support of U.S.- Zambia Trade and Investment Workshop* (Year 5 Annual Plan #9)

On March 13 and 14, 2018, the Standards Alliance organized a two-day workshop in Lusaka, Zambia, focused on further engagement between the U.S. and Zambia economies. The workshop highlighted the importance of standards in supporting U.S. business investment and the growing demand for quality products in the East African country.

More than 64 participants attended the workshop from the public and private sector and featured presentations on the U.S. standards and conformity assessment system, as well as, standards-related topics in three priority sectors: infrastructure, energy, and agriculture. The event included speakers from seven U.S. participants representing the American Society of Agricultural and Biological Engineers (ASABE), ASTM International, Deytec Inc., the Grocery Manufacturers Association (GMA), the Midwest Organic and Sustainable Education Service (MOSES), Tri-Environmental Inc., and Underwriters Laboratories Inc. (UL). Zambian speakers included representatives from the USAID Southern African Trade and Investment Hub (SATIH), the Zambian Bureau of Standards (ZABS), and the Zambian Association of Manufacturers (ZMA).

The workshop emphasized the importance of standards and quality in supporting U.S. business investment in Zambia, and highlighted the value of a stable and predictable regulatory environment for interested investors. Similarly, speakers emphasized the role of standards in supporting the demand for quality products and services by Zambia's rapidly expanding middle class.

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

ANSI and the Business Regulatory Review Agency (BRRA) of Zambia have been coordinating to outline the structure and logistics for a July training for Zambian

regulators to better understand and perform a regulatory impact assessment. ANSI is also working with Nathan Frey, formerly of OMB-OIRA, as a consultant to develop workshop materials.

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	Indonesia	Water for Indonesia Now – community challenge and accreditation transfer	Yes
4	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	Yes
5	Peru	ASME Advanced Manufacturing Workshop	No
6	West Africa	West Africa Training on Textiles and Apparel Standards	Yes
7	West Africa	Risk-Based Consumer Protection Follow-up Roadshow	Yes
8	West Africa	National Enquiry Point/National Notification Authority Trainings	No
9	Mozambique	Workshop on Good Regulatory Practices	Yes
10	Zambia	Standards to Support U.S. – Zambia Trade and Investment	Yes
11	Zambia	Technical Training on Regulatory Impact Assessment	Yes
12	Southern, East, and West Africa	U.S. presentation and panel participation at the ARSO General Assembly	No
13	Jordan-Middle East and North Africa (MENA)	IAPMO engagement with JSMO, RSS and MWPH	Yes

This period of performance included a combination of execution and planning for future activities some of which will take place in the second and third quarter of 2018. The outcomes witnessed in Q1 are positive and represent the continued success of the Standards Alliance program.

In particular, activities carried out through the AdvaMed-led initiative in Latin America have helped advance discussions with key regulators in Colombia on the utility and advantages of health regulator mandates and the impact of GRP policies on Colombian Medical Device Regulation and Standardization. These meetings have also advanced the goal of INVIMA joining IMDRF and implementing GRP policy for the INVIMA Medical Device division and the Ministry of Health. Key outcomes were also realized in Indonesia, where IAPMO doubled the number of toilets and hand washing facilities in Cicau village, with improved drainage, light, ventilation, access and security.

CONCLUSION

This period of performance achieved important milestones for the Standards Alliance such as the continued implementation of AdvaMed's work plan with medical device regulators in Latin America, continued development and enforcement of plumbing codes and standards in Indonesia and the implementation of key workshops in Zambia 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, Mozambique, Zambia, Colombia, Peru, CAFTA-DR and other partners.