

Period of Performance: July 1 – September 30, 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 third 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 Mozambique, Latin America and Vietnam; as well as planning for fourth quarter 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. This also included the addition of a West Africa page reflecting the Trade Africa expansion and other new features. 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- (Added to Year 4 Annual Plan in Q1)*

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

During the third quarter to 2017, AdvaMed continued implementation of its work plan with medical device regulators in Mexico, Colombia, El Salvador and the Pan-American Health Organization (PAHO). In line with deliverables set out for Tier 1 Phase 1, AdvaMed completed the development and translation of the expanded version 2.0 guidance document. Work under Tier 1 Phase 2, the regulatory coherence gap analysis, continued steadily and is expected to be completed by the end October 2017. The Colombian medical device regulatory agency (INVIMA) agreed to participate in Tier 2 Phase 3 of the Standards Alliance project and expressed interest in leveraging the Standards Alliance to further its work (Tier 2 Phase 4).

Planning continued with PAHO for a follow-up Tier 2 Phase 4 workshop. The workshop will take place in February 2018 in Mexico City in conjunction with the next COFEPRIS Center of Excellence event. Meetings are currently being confirmed for the Tier 1 Phase 3 bilateral engagement with the Regulatory Coherence authorities in Mexico City, Bogotá, Lima, and San José, Costa Rica in October 2017. A Tier 1 Phase 4 Regulatory Coherence Workshop with these authorities is being considered for either Nov-Dec, 2017 or Q1, 2018.

Indonesia

- *IAPMO Water for Indonesia Now project – (Year 4 Annual Plan #7)*

In Q3 IAPMO completed the initial effort to transfer KAN Accreditation for ISO 9001 certification program. Beginning late August, all of ISO 9001 certification is being processed in Indonesia. Q3 also marks an important milestone for Indonesia office with the completion of the first complete testing of faucets and floor drains collected on project site by BSN team. In Q3 we also received our initial recognition from IAPMO R&T as one of their recognized laboratories allowing Indonesia office to serve testing needs for IAPMO R&T's listees in the region. During Q3, several initiatives took place. A few of the initiatives are as follows: approached Green Product Council Indonesia for appointment as their third party verification agency, approached several local hotel chains to offer plumbing systems inspection in accordance with SNI 8153:2015 for their hotel facilities, and officially submitted our application to the Ministry of Industry to appoint IAPMO as one of the approved testing and certification agency for their Water Closet mandatory standard.

In addition, An International Team comprising young Plumbers, Plumbing Engineers and Architects from Indonesia, Australia and the USA have successfully completed the first ever Community Plumbing Challenge Design Week, marking the beginning of the Community Plumbing Challenge 2017 program (CPC2017) in Cikarang, Bekasi (West Java), Indonesia.



From 31 July to 3 August 2017, the group were welcomed to Sekolah Dasar Negeri (public elementary school) Cicau 02 in Cicau Village, Cikarang, where they completed a surveying and design process over four days in full consultation with school management and with further input from teachers and schoolchildren. A

sustainable upgrade solution for water supply, wastewater and hand washing at the school was the objective of this collaboration. WASH educational activities was complemented with a series of games and activities presented to the schoolchildren – aimed at different age groups, and delivered both inside the classroom and outside in the playground and surrounding school grounds – that demonstrated key ideas linking personal health and hygiene to water, sanitation and design thinking.

- *Phase II, Food Additives Workshop in Indonesia and Vietnam (New addition to Year 4 Annual Plan)*

The Standards Alliance with the support of the U.S. Department of Agriculture (USDA) and the International Life Sciences Institute (ILSI) organized 2 follow-up workshops on food additives in Hanoi, Vietnam and Jakarta Indonesia on July 11 and 13, 2017. The workshops were intended to develop capacity in these emerging markets on food additive issues, particularly focusing on global harmonization, basing regulatory policy on science, increasing understanding of toxicological assessments, improving risk communication and fostering a more collaborative environment for industry and government cooperation on these issues.

The July 11 workshop in Hanoi, Vietnam focused on the global approaches and processes on food additive safety assessment, risk communication, harmonization and partnership in regulatory development, as well as technical barriers to trade in relation to food additives. More than 100 participants including regional regulators, academics and industry attended the event. Representatives from the American Beverage Association (ABA), International Council of Grocery Manufacturers Associations (ICGMA), ILSI-SE Asia and Calorie Control Council (CCC) presented the U.S. perspectives. Since the seminar

some Vietnam Food Administration (VFA) staff have requested follow-up activities-i.e. additional workshops/trainings or technical support on the development and implementation of food additives regulations.

The workshop on July 13 in Jakarta, Indonesia addressed the same topics covered in Hanoi. The seminar was attended by more than 90 participants. Participants included Indonesian government representatives from the National Agency of Drugs and Foods Controls (B POM), the Ministry of Agriculture (MOA), Ministry of Trade (MOT) and Ministry of Research , Technology and Higher Education, as well as, participants from industry. Since the seminar, officials from B POM have expressed interest in future workshops/trainings on food ingredient regulations.

Jordan – Middle East and North Africa (MENA)

- *IAPMO engagement with JSMO, MPWH, and RSS (Added to Year 4 Annual Plan in Q1)*

As part of the USAID-Standards Alliance funded Middle East Project, IAPMO continues to work with staff 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 to define the scope of our partnership and to outline the funding requirements. During this quarter, all partners approved an MOU outlining the partnership and its goals. IAPMO is currently working with Jordanian stakeholders to set a date in Q4 for an MOU signing event. IAPMO also continues to be in communication with US Commercial Service staff and USAID contactors who are tasked with leading a new water demand management project in Jordan.

- *Standards Alliance Automotive Discussion with SASO and GSO in Riyadh (New addition to Year 4 Annual Plan)*

On 27 September, Standard Alliance in partnership with the Department of Commerce hosted an automotive discussion with representatives from SASO and GSO in Riyadh, Saudi Arabia. The discussions were very productive and presented various opportunities for follow-up. DoC has expressed an interest in having the same discussions with representatives from ESMA, who were unable to join the meeting in Riyadh. The DoC is planning to arrange a video discussion with them in the coming months and is interested in collaborating with ESMA on the data collection discussion and a possibly rolling out ESMA's specialty parts regulation.

While this effort was conducted under the Standards Alliance umbrella as a continuation of DoC and the auto industry's work in Vietnam and Latin America, the industry and DoC funded the activity in Riyadh and no Standards Alliance funds were applied.

Peru

- *Planning for ASME Advanced Manufacturing Workshop (New addition to Year 4 Annual Plan)*

The Standards Alliance is currently in discussions of ASME and considering a two-day workshop designed to provide knowledge and tools required to participate in the advanced manufacturing industry. The workshop is set to take place in November 2017 and EngineZone is expected to collaborate with ASME for this workshop. The workshop will also include details on the latest technological advancements currently being incorporated in international standards. Speakers will include ASME's subject matter experts (SMEs) who are highly qualified and possess knowledge of international standards used in the Advanced Manufacturing Industry, specifically Geometric Dimensioning and Tolerancing (GD&T) applications including ASME Y14.5, ASTM F42, ISO/TC 261, ASME B.46, and ASME Y14.46.

Mozambique

- *Workshop on Using the Mozambique National Quality Policy to Promote Trade and Investment (Year 4 Annual Plan #17)*

On August 10, 2017, the Standards Alliance organized a one-day workshop in Maputo, Mozambique in partnership with Instituto Nacional de Normalizacao e Qualidade (INNOQ). The event, titled "Using the National Quality Policy to Promote U.S. – Mozambique Trade and Investment," was attended by 72 participants from the public and private sector. The workshop featured presentations from U.S. and Mozambican representatives, including participants from Bureau Veritas, Bristol-Myers Squibb (BMS), Underwriters Laboratories (UL), Regulatory Strategies and Solutions Group (RSS Group), INNOQ, and the Mozambican Ministry of Industry and Commerce (MIC). Workshop presentations supported Mozambique's ongoing national quality policy development and provided an opportunity for participants to consider ways to use their draft national quality policy to enhance bilateral trading relationships between the U.S. and Mozambique.

Southern Africa

- *Planning for Standards Alliance Participation in ARSO CACO Meeting in Namibia (New Addition to Year 4 Annual Plan)*

The Standards Alliance is planning U.S. participation at the October African Organization for Standardization (ARSO) Conformity Assessment Committee (ARSO CACO) meeting in Swakopmund, Namibia. During this year's CACO Meeting, a U.S. expert, sponsored by the Standards Alliance, will provide a presentation covering the components and usage

of the American National Standard for Sustainable Agriculture (ANSI/LEO-4000) and elaboration on U.S. sustainable agriculture standards.

Vietnam/ASEAN

- *Standards Alliance Workshop on Sharing Best Practices in Chemicals Regulation (Year 4 Annual Plan #18)*

On August 22-23, the Standards Alliance and the American Chemical Council (ACC) organized a workshop on "Sharing Best Practices in Chemical Regulation" in Ho Chi Minh City, Vietnam. The workshop took place on the sidelines of the annual APEC meetings and was an extension of the 2014, Beijing Regulatory Cooperation Workshop designed to deepen knowledge management in regulatory cooperation, through a capacity-building training program for APEC regulators.

The overall objective of the program was to link regulator knowledge with practical application. It was designed to enhance regional economic integration in chemicals through knowledge sharing, capacity building, and regulatory cooperation and convergence. Workshop participants were able to exchange information on best practices in the sound management of chemicals, in order to increase the capability and capacity of developing economies. 13 APEC member countries attended the event including over 75 participants presenting public and private sector organizations, i.e., the Ministry of Health of Chile, the Federation of Thai Industries, United States Environmental Protection Agency (EPA), U.S. Department of Labor, OMB OIRA, BOYSEN, ASTM International and many more.

- *Phase II, Food Additives Workshop in Indonesia and Vietnam (New addition to Year 4 Annual Plan)*

See summary above.

- *Vietnam Delegation of Autos Officials Visit to the U.S. (New addition to Year 4 Annual Plan)*

On September 11-15, 2017, the Standards Alliance together with the U.S. Department of Commerce (DoC) and the American Automotive Policy Council (AAPC) organized a detailed autos delegation visit to Washington, D.C, Columbus, OH, and Detroit, MI. Three representatives from the Vietnam Register participated in the week-long event. The idea for the training session came at the suggestion of the National Highway Traffic Safety Administration (NHTSA) during the APEC meetings earlier this year.

The workshop provided a great opportunity for U.S. auto industry to share useful information and firsthand experience with the participants to help improve quality certification and testing systems for motor vehicles in Viet Nam. The event incorporated

discussions and visits with experts from across the government, including the Department of Transportation (DOT) - NHTSA, FCSMA and VRTC, U.S. Environmental Protection Agency (EPA), as well as industry, including AAPC members; Navistar, General Motors, Ford and Fiat Chrysler Automobiles. Participants visited the Stonebridge Hi-stat manufacturing facility, the Vehicle Research & Testing Center, Navistar's Facility in Ohio and Ford's Emissions Lab in Michigan

- *IAPMO engagement with Government of Vietnam (Added to Year 4 Annual Plan in Q1)*

In July 2016, IAPMO participated in a U.S. Department of Commerce led trade delegation focusing on water infrastructure in Singapore, Vietnam, and the Philippines. During the course of the trip, IAPMO learned that because of the assistance it provided there is still a great deal of goodwill towards it by the various ministries. IAPMO also learned that the Ministry of Construction, which oversees the mandatory building codes, has taken steps to update its plumbing code. It has tasked the National Institute of Architecture to spearhead this effort. Additionally, Vietnam's Directorate for Standards, Metrology, and Quality (STAMEQ) is very interested in moving forward with water efficiency product standards.

During Q3 2017, IAPMO traveled to Ho Chi Minh City to participate with STAMEQ in highlighting the important role water/sanitations standards play in developing smart cities. This workshop was held in conjunction with the APEC SOM3 meetings. Additionally, IAPMO traveled to Hanoi to meet with the Ministry of Construction to discuss the draft MOU outlining a potential partnership between IAPMO and the Vietnamese government. For the meeting, the Ministry of Construction assembled all of the relevant ministries and officially created a taskforce to update the plumbing code. IAPMO continues to be in touch with the MOC, the National Institute of Architecture and the Institute of Building Sciences and Technology on the development of the new code.

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

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

On October 10-13, 2017, the Standards Alliance will organize a four-day training activity in Washington, DC. The orientation visit intends to cover topics related to "A Risk-Based Approach to Consumer Protection," with the primary goal of helping West African countries strengthen their risk-based consumer protection systems.

The visiting delegation will include delegates from Cote d'Ivoire, Senegal, and Ghana and one observer from Nigeria. Visiting delegates include participants from CODINORM, the Association to Promote Ivoirian Exports (APEXI-CI), the Ivorian Ministry of Commerce, the Ghana Standards Authority (GSA), the Ghanaian Ministry of Trade and Industry

(MOTI), Ghana Food and Drug Authority (FDA), the Senegalese Internal Trade Department (DCI), and the Standards Organization of Nigeria (SON).

Zambia

- *Planning for Standards in Support of U.S.- Zambia Trade and Investment Workshop (Year 4 Annual Plan #15)*

The Standards Alliance is organizing a 1 to 2 day workshop in Zambia currently planned for the week of December 4, 2017 in Lusaka, Zambia. The focus of the workshop will be “Standards to support U.S. - Zambia trade and investment” and will focus on five critical sectors to the Zambian economy: infrastructure, energy, chemicals, mining, and agriculture. ANSI is currently recruiting U.S. speakers for this workshop. ANSI will work with interested speakers to refine the draft agenda.

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	Indonesia	Phase II, Food Additives Workshop in Indonesia and Vietnam	No
5	Mozambique	Workshop on Using the Mozambique National Quality Policy to Promote Trade and Investment (Year 4 Annual Plan #17)	Yes
6	Vietnam-ASEAN	Standards Alliance & APEC Chemical Dialogue - (Year 4 Annual Plan #18)	Yes
7	Vietnam-ASEAN	Vietnam Delegation Visit to the U.S.	No
8	Vietnam-ASEAN	IAPMO workshop with STAMEQ	Yes
9	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
10	Jordan-Middle East and North Africa (MENA)	Standards Alliance Automotive Discussion with SASO and GSO in Riyadh	No

11	Jordan-Middle East and North Africa (MENA)	IAPMO engagement with JSMO, RSS and MWPH	Yes
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This period of performance included a combination of execution and planning for future activities some of which will take place in the final quarter of 2017. The outcomes witnessed in Q3 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 started to gain recognition in the medical device industry and beyond. The Regulatory Coherence Implementation Guideline in English, Spanish and Portuguese has been touted by various U.S. groups including the Americas Business Dialogue (ABD) and its Regulatory Working Group together with its secretariat, the Inter-American Development Bank (IDB). These groups have secured their consensus to have the Summit of the Americas CEOs and Leaders endorse the adoption of Regulatory Coherence policies across the Western Hemisphere at its upcoming April 2018 meeting in Lima, Peru. Further endorsements from key players like the National Institute for Food and Drug Administration (INVIMA) (Colombia), PAHO and the Brazilian Inter-Ministerial Trade Chamber (CAMEX) will be instrumental in ensuring successful implementation of deliverables in Colombia, Mexico, Peru, CAFTA-DR.

Activities carried out with visiting delegations from Vietnam, and the upcoming West Africa visit have proved to be extremely beneficial in opening new channels for cooperation, capacity building and information sharing to bolster trade and investment in these economies.

CONCLUSION

This period of performance achieved important milestones for the Standards Alliance such as the implementation of the Mozambique National Quality Policy workshop, the APEC Chemicals Dialogue and the Phase II Food Additives Workshop in Indonesia and Vietnam. The Standards Alliance also witnessed significant progress toward completion of the 4th year’s activities. ANSI looks forward to building off these successes in the next period and carrying out activities with Zambia, Colombia, Mexico, Peru, CAFTA-DR and other partners.