



**Period of Performance:** April 1 – June 30, 2017

## INTRODUCTION

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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 second 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

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This period of performance was dedicated primarily to implementation of activities described in the country-specific work plans in Zambia, Latin America and Jordan; as well as planning for third and 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.

### Indonesia

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

IAPMO continues to work on expanding its testing and certification capabilities for Indonesia with a target date for the scope expansion accreditation audit in July and August 2017. In addition to purchasing of additional testing equipment, IAPMO has also

hired a Business Development Manager with nearly 20 years of work experience in the certification field for local market. Additionally, IAPMO is preparing to transfer its KAN accreditation for ISO 9001 and ISO 14001 management systems certification program to its Indonesia office with audit dates on July and September 2017.

In addition, a meeting is in the works with the Ministry of Industry to pursue official appointment as an approved testing body and certification body for water closets. Meetings with Green Building Council Indonesia and Green Product Council Indonesia for collaboration and partnership possibility in the area of plumbing testing and certification will also take place. PT IAPMO Group Indonesia is preparing to participate in the Indowater Show on July 12-14 in Jakarta to promote its services. Lastly, plans are in place to renew the cooperative MoU with BSN in July 2017.

#### 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.

During the second quarter of 2017, AdvaMed completed the translation of the Regulatory Coherence (Good Regulatory Design) Implementation Guide into Spanish and Portuguese. The Guide was completed during Q1 and is available on the [website](#). The expanded version 2.0 of the guide, with information specific to the medical device sector, is currently in development. AdvaMed is in the process of conducting national assessments and gap analyses for four countries: Costa Rica, Colombia, Mexico, and Peru with an estimated completion of September 2017.

Tier 1 and Tier 2, Phase 2, gap analysis and assessment began in May 2017 and Tier 1 & 2 of Phase 3, creation and execution of implementation plans to address sector-specific issues in each project country and 4, establish a forum to share best practices between medical device Good Regulatory Practices, technical regulations, standards, and conformance policy implementing teams from participating countries, are scheduled to begin by Q4, 2017.

## Jordan – Middle East and North Africa (MENA)

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

On April 24-26, 2017, the Standards Alliance in partnership with the Office of the United States Trade Representative (USTR) and the GCC Standardization Organization (GSO) held a 3-day workshop entitled “U.S.-Gulf Conference on Good Regulatory Practice and Regulatory Impact Assessment” in Riyadh, Saudi Arabia. The workshop was originally proposed by Nabil Molla, secretary general of GSO, to provide an opportunity for U.S.-GSO cooperation and strategic exchange. In order to maximize impact in the region, two participants from the Jordan Standards and Metrology Organization were also invited to the workshop. Topics of focus included: GRP principles, use of international standards and conformity assessment procedures, scientific and evidence-based rulemaking, regulatory impact assessment (RIA), public consultation and advancements in E-rulemaking and best practices for regulatory cooperation.

More than 45 participants representing public and private sector organizations in the gulf region attended the workshop including, the Saudi Standards, Quality and Metrology Organization, (SASO) Saudi Food and Drug Authority, Alsafi Danone Co.Ltd, Emirates Authority For Standardization and Metrology (ESMA) among others. Speakers from U.S. represented the USTR, Environmental Protection Agency (EPA), Office of Management and Budget (OMB-OIRA), ASTM International, Intertek, Red Wing Shoe Company, American Chemical Council (ACC), Procter & Gamble. This was the biggest U.S. delegation yet to travel in support of a Standards Alliance Workshop.

Key outcomes from the workshop included an invitation from the GSO for U.S. experts to participate in a workshop to be held later in 2017 on the subject of conformity assessment and mutual recognition schemes. In addition, Red Wing Shoe Company addressed key market access concerns in Saudi Arabia through dialogue with SASO.

- *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 continued to review and refine a draft MOU outlining the partnership and its goals. Pending final approval, IAPMO will work with Jordanian stakeholders to set a date in Q3 or Q4 for an MOU signing event. IAPMO has also been working with USAID contractors who are tasked with leading a new water demand management project in Jordan.

## Mozambique

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

In support of the first activity in ANSI's work plan for Mozambique, ANSI worked with its local partner, INNOQ, and relevant USAID Missions to secure dates and agree on concepts for a training program based on Mozambique's draft national quality policy, which will guide the development of robust national quality infrastructure.

The training will focus on public consultation and participation of the private sector in standards development and rulemaking. This training is scheduled to take place in on August 10, 2017.

## Zambia

- *Zambia Workshop on Regulatory Impact Analysis (Year 4 Annual Plan #14)*

On April 24-25, the Standards Alliance implemented the "Workshop on Regulatory Impact Analysis (RIA), Risk Analysis and Public Consultation" in Zambia. The event was co-hosted by the Zambian Bureau of Standards (ZABS) and Zambia's Business Regulatory Review Agency (BRRRA). The workshop focused on good practices in the development and implementation of RIA as well as the role of the private sector in RIA.

The workshop was attended by 41 participants from the public and private sector and featured presentations from the U.S. and Zambia, including representatives from General Electric (GE), Regulatory Strategies and Solutions Group (RSS Group), the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), BRRRA, and ZABS. Workshop presentations supported the Zambian government's ongoing emphasis on RIA and provided an opportunity for Zambian participants to become more familiar with the process of RIA and the role of private-sector participation in the regulatory process.

Preceding the workshop, BRRRA released the "Handbook for Undertaking Regulatory Impact Assessment," which provides a framework for Zambian government agencies to perform RIA. It is the first Zambian document to describe a systematic procedure for the development and implementation of government policies and legislation.

RIA is the process of analyzing the costs and benefits of policy and regulation changes to ensure that regulatory decisions are well-informed and cost effective. Effective RIA can help countries like Zambia enhance domestic regulatory quality by proactively identifying and avoiding regulatory inefficiencies. This process can improve social welfare and augment economic growth, while creating a more business-friendly environment.

## Vietnam/ASEAN

- *Planning for the ANSI – Standards Alliance & APEC Chemical Dialogue - (Year 4 Annual Plan #18)*

The Standards Alliance and the American Chemical Council (ACC) are planning a workshop on Sharing Best Practices in Chemical Regulation in Ho Chi Minh City, Vietnam on August 22-23 as part of the third APEC Senior Officials Meeting (SOM 3). The workshop will highlight best regulatory practices in the chemicals sector and includes speakers from Office of the United States Trade Representative (USTR), the Occupational Safety and Health Administration (OSHA), the U.S. Environmental Protection Agency (EPA), ACC, and Exxon Mobil.

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

- *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 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 on October 9 -13, 2017.

## EVALUATION OF ACTIVITIES

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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 – testing and certification program development	Yes
4	Mozambique	Planning for training programs in Mozambique on Good Regulatory Practices (Year 4 Annual Plan #17)	Yes

5	Zambia	Zambia Workshop on Regulatory Impact Analysis (Year 4 Annual Plan #14)	Yes
6	West Africa	Planning for Risk-based Consumer Protection Orientation Delegation visit by Senegal, Ghana, and Cote d'Ivoire (Year 4 Annual Plan #23)	Yes
7	Vietnam-ASEAN	Planning for ANSI – Standards Alliance & APEC Chemical Dialogue - (Year 4 Annual Plan #18)	Yes
8	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
9	Jordan-Middle East and North Africa (MENA)	U.S. – Gulf Conference on Good Regulatory Practices and Regulatory Impact Assessment (Year 4 Annual Plan #10)	Yes
10	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 the planning of future activities, many of which will take place in Q3 and Q4 of 2017. The outcomes witnessed were positive and represent the continued success of the Standards Alliance.

In particular, outcomes have begun from the AdvaMed-led initiative on regulatory convergence in Latin America. With the translation and dissemination of the good practices guide, and the gap analyses being conducted for each partner country, the medical devices industry is making great strides forward in achieving its goals related to regulatory infrastructure in key markets like Colombia and Mexico.

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## CONCLUSION

This period of performance achieved important milestones for the Standards Alliance such as the implementation of a good regulatory practices conference with Jordan and the Gulf States in Saudi Arabia 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 4<sup>th</sup> year's activities. ANSI looks forward to building off these successes in the next period and carrying out activities with Vietnam, West Africa, Colombia, Mexico, Peru, CAFTA-DR and other partners.