



**Asia-Pacific  
Economic Cooperation**



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# **Good Regulatory Practices for Conformity Assessment in APEC Member Economies**

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# Abstract

Government regulators often require demonstration that products and production processes meet minimum standards for health, safety, and environmental protection. Conformity assessment provides ways to show compliance with technical regulations. Although conformity assessment can be beneficial, it can also impede trade if conducted inappropriately or in a non-transparent manner.

Drawing on work by the APEC Subcommittee on Standards and Conformance (SCSC) on good practices in technical regulation, this survey-based report examines how APEC member economies ensure that regulatory policies protect health, safety and the environment while promoting free trade in the Asia-Pacific region. The report summarizes member economies' preferred approaches to and practices in conformity assessment and the laws governing such practices, and examines the application of international standards to conformity assessment, cooperation among member economies, and member economies incorporate good practices into assessment requirements. It also describes member economies' mandatory assessment requirements for electrical installations, photovoltaic products, and medical devices/pacemakers. The report also offers observations as the basis for further improvement in conformity assessment approaches in member economies.



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# Acronyms and Abbreviations

ACCSQ	ASEAN Consultative Committee for Standards and Quality
ANAB	ANSI-ASQ National Accreditation Board
APEC	Asia-Pacific Economic Cooperation
APLAC	Asia Pacific Laboratory Accreditation Cooperation
ASEAN	Association of Southeast Asian Nations
CA	Conformity assessment
CAB	Conformity assessment body
CASCO	ISO Conformity Assessment Committee
CB	Certification body
CITEL	Inter-American Telecommunication Commission
COPANT	La Comisión Panamericana de Normas Técnicas
EE	Electrical and electronic
EEA	European Economic Area
EFTA	European Free Trade Association
EMA	Entidad Mexicana de Acreditación
EMC	Electromagnetic compatibility
EMS	Environmental management systems
EU	European Union
EurAsEC	Eurasian Economic Community
FTAs	Free trade agreements
GCC	Gulf Cooperation Council
GCC	Gulf Cooperation Council
GMPs	Good manufacturing practices
GRPs	Good regulatory practices
GSO	GCC Standardization Organization
IAAC	InterAmerican Accreditation Cooperation
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
IECEE	IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
JAB	Japan Accreditation Board
JAS-ANZ	Joint Accreditation System of Australia and New Zealand
LV	Low voltage
MDPWG	Medical Device Product Working Group
MEELS	Mandatory Energy Efficiency Labeling Scheme (Hong Kong, China)
MLA	Multilateral recognition arrangements
MOUs	Memorandum of understanding

MRAs	Mutual Recognition Agreement
NCBs	National certification bodies
NTTAA	National Technology and Advancement Act
OECD	Organisation for Economic Co-operation and Development
OMB	Office of Management and Budget
PAC	Pacific Accreditation Cooperation
PACER	Pacific Agreement on Closer Economic Relations
PASC	Pacific Area Standards Congress
PIC/S	Pharmaceutical Inspection Convention and Inspection Cooperation Scheme
POLEVAS	Policies and procedures for conformity assessment
PVs	Photovoltaics
QMS	Quality management systems
RCEP	Regional Comprehensive Economic Partnership Agreement
RIA	Regulatory impact analysis
SCSC	Sub-Committee on Standards and Conformance
SDoC	Supplier Declaration of Conformance
SOM	Senior Officials Meetings
SPRING	SPRING Singapore (agency under the Ministry of Trade and Industry)
TATF	Technical Assistance and Training Facility
TBT	Technical Barriers to Trade
TEL	Telecommunications
TGA	Therapeutic Goods Administration
TPP	Trans-Pacific Partnership Agreement
USA	United States of America
WG	Working group
WTO	World Trade Organization

# Executive Summary

For nearly two decades, APEC has led international discussion on mitigating the negative impact of regulatory divergence on trade and investment and on strengthening application of WTO principles to reduce obstacles to trade arising from divergent approaches to regulation and conformity assessment in the Asia-Pacific region.

The Sub-Committee on Standards and Conformance (SCSC), which is under APEC's Committee on Trade and Investment, provides policy recommendations regarding good practices in technical regulation. This survey-based report provides an overview of APEC member economies' approaches to and practices in conformity assessment and suggests how they can apply assessment practices more efficiently and still facilitate trade. The survey responses indicate considerable agreement among member economies that good regulatory practice (GRP) in conformity assessment has economic and social benefits and improves access to markets, regional and international—and that cooperation can better align practices, build trust, and mitigate the negative impact of regulatory divergence. Responses also indicate that there are challenges in implementing WTO principles and securing the benefits that come with regulatory cooperation and harmonization.



# 1. Introduction

APEC member economies are committed to regulatory policies that contribute to the protection of health, safety and the environment and the promotion of free trade in the Asia-Pacific region. For nearly two decades, APEC has led international discussion on the importance of good regulatory practice (GRP) to trade and investment; has strong programs in the Economic Committee, Industry Dialogues, and the Sub-Committee on Standards and Conformance (SCSC); and has held a biennial conference on GRP since 1998. Good practices in conformity assessment, particularly as they relate to regulations, are integral to GRP in general.

APEC's GRP work has improved the effectiveness and the efficiency of regulations in achieving their objectives; helped to eliminate or avoid unjustified, excessive, and burdensome requirements; and led to approaches compatible with economic growth, business development, and job creation without compromising environmental, health, and safety protections. That work has also exemplified an integrated approach to rule-making and emphasized good governance principles, such as accountability, consultation, and transparency, all of which are applicable to conformity assessment.

The United States has advanced implementation of GRP in APEC, making it a topic of the Senior Officials Meetings (SOM) 1 in Washington, D.C., in March 2011. At the SCSC's sixth conference on GRP, member economies discussed ways to strengthen implementation of GRP, including ways to reduce trade barriers related to conformity assessment. APEC TATF then funded a 2011 study, "Supporting the TBT Agreement with Good Regulatory Practices - Implementation Options for APEC Members," authored by Scott Jacobs. In March 2012, the SCSC endorsed the report, which provides background and information for this report.

Funded by APEC TATF, this report should help make the achievement of regulatory objectives more efficient and effective while minimizing the burden imposed on manufacturers and industry. It provides an overview of member economies' conformity assessment approaches and practices in meeting regulatory objectives and facilitating trade, and examines conformity assessment in several sectors as indicative of varying approaches in member economies. The scope is limited to governments' assessment practices as a first step in understanding practices and approaches in the APEC region. Information for the study was collected through an online survey (<http://www.surveymonkey.com/s/KVKBPMY>), and a preliminary verbal report was presented to the SCSC at the 7<sup>th</sup> Conference on Good Regulatory Practices in Medan, Indonesia, on June 26-27, 2013.

## **BENEFITS OF CONFORMITY ASSESSMENT**

As defined in ISO/IEC 17000:2004, conformity assessment is a "demonstration that specified requirements relating to a product, process, system person or body are fulfilled." Conformity assessment consists of sampling, testing, inspection, supplier's declaration of conformity,

product certification, management system certification, and third-part accreditation of the competence of a body to carry out these activities.

The choice of assessment processes, as well as the competence with which any one of them is performed, has a significant effect on confidence in and the reliability of the entire assessment. Government regulators, for example, need to be confident that requirements for safety, health, environmental protection and fair commerce have been met.

Article 9 of the WTO Agreement on Technical Barriers to Trade (TBT Agreement), requires that members, wherever practicable, formulate and adopt international systems of conformity assessment where a positive assurance of conformity with a technical regulation or standards is required. In the Fifth Triennial Review, WTO members agreed to describe in the TBT Committee their experience with conformity assessment procedures, with a view to understanding how to facilitate acceptance of assessment results.

## **OBSERVATIONS**

The good news is that conformity assessment infrastructure in APEC member economies is strong and getting stronger. In addition, assessment procedures do facilitate trade when their results are accepted with confidence.

Most member economies use conformity assessment mechanisms that are based on international principles and standards. They also recognize and apply international standards for conformity assessment and follow voluntary arrangements in certain sectors. They should consider fostering the use of these proven mechanisms in other sectors as well.

Some economies need to raise awareness of the value of international approaches to conformity assessment. This includes encouraging the use of all options provided by international standards, such as first-party declaration of conformity in conjunction with other mechanisms or by itself. The survey responses seem to indicate overuse of third-party certification at the expense of other forms of conformity assessment.

All economies need to raise awareness and understanding of the conformity assessment provisions of the TBT Agreement, particularly those related to notification of proposed assessment procedures, as well as other provisions in Article 5. For example, applying international standards for the operation of conformity assessment bodies is laudable and meets TBT requirements but in and of itself is only one aspect of good practice. Just as important are Article 5 provisions on the national treatment of products; on limiting information to what is necessary to assess conformity; on the confidentiality of this information; on the need for equitable fees; and on the need for expeditious completion of the work. Accreditation is an excellent means for ensuring the competence of conformity assessment bodies and is mentioned in the TBT Agreement but in and of itself does not constitute good practice. Good practice is the sum of a wide range of practices and attributes called out in the TBT Agreement and others.

GRP implementation will go a long way in ensuring that conformity assessment procedures do not impede international trade and are not applied more strictly than necessary. To foster trade, economic development, and competitiveness, governments should strive to have requirements that are the least burdensome while still ensuring that their legitimate objectives are met. Good practice will then have been achieved.

## 2. Summary of Survey Responses

This overview is based on the survey responses provided by the 21 APEC economies. The survey was conducted from January to June 2013. It consisted of 14 questions, 13 requesting information on assessment practices and approaches. The first asked for the name of the respondent and contact information. A summary of the responses to each question follows. The full text of questions and responses from each economy are provided in Appendix A.

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### ***2. Are there laws, regulations, rules or formal guidance that specify a general policy on conformity assessment? If “yes”, please provide the text or a link to it.***

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A little more than half of APEC economies indicated that they have such laws, regulations, rules or formal guidance (Australia, China, Chile, Indonesia—expected in 2014—Malaysia, Mexico, Papua New Guinea, Republic of Korea, Russia, Chinese Taipei, the United States, Viet Nam). Though Brunei, Hong Kong China, Japan, Peru, The Philippines, New Zealand and Singapore indicated that they do not, most of them stated that they have specific laws or rules for different regulatory areas. Some, like Canada and Malaysia, mentioned accreditation policies but it is not clear how such policies constitute a policy on conformity assessment. Among economies that responded positively, approaches vary widely.

- Australia has no specific law or regulation but has handbooks with general policy on regulatory practice that includes conformity assessment.
- Brunei has a regulation titled “the Consumer Protection (Fair Trading) order 2011.”
- China has regulations on certification and accreditation ([www.cnca.gov.cn](http://www.cnca.gov.cn)).
- Chile has Decree 77-Ministry of Economy, which establishes requirements for adoption and application of technical regulations and conformity assessment procedures.
- Indonesia has a regulation 102-2000 on domestic standardization and is drafting an act that will include conformity assessment.
- Japan does not have such laws, regulations, rules, or formal guidance.
- Mexico laws on metrology, technical regulations, standards and conformity assessment: “Ley Federal sobre Metrología y Normalización,” “Reglamento de la Ley Federal sobre Metrología y Normalización,” and “Políticas y procedimientos para la evaluación de la conformidad y sus modificaciones” (POLEVAS).
- New Zealand does not have a policy on conformity assessment.

- Papua New Guinea's "National Institute of Standards & Industrial Technology Act of 1993" includes conformity assessment in Sections 5 (1e), 5(1f) and 5 (1j).
- Peru has a law on National Systems of Standardization and Accreditation (Legislative Decree 1033) but it does not include a policy on conformity assessment.
- The Philippines has no general policy but specific laws for different regulatory agencies.
- Republic of Korea has the Framework Act on National Standards describing the domestic policy on conformity assessment in Articles 21, 23 and 25.
- Russia has a federal law 184-FZ, 27 December 2002, with several amendments.
- Singapore has no general policy but three specific regulations for consumer products and controlled goods.
- Chinese Taipei has "The Commodity Inspection Act." Products under the jurisdiction of other regulatory authorities are covered by separate laws.
- Thailand does not have a general policy.
- The USA's NIST provides guidance to federal agencies on conformity assessment as directed by "The National Technology and Advancement Act" (NTTAA) and OMB Circular A-119.
- Viet Nam has a policy included in the law on standards and technical regulations ([www.tcvn.gov.vn](http://www.tcvn.gov.vn)).

### **3. What is your government's preferred conformity assessment approach?**

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*Based on alignment of international practices and ISO/IEC standards and guides where applicable (Brunei, Korea, Mexico, The Philippines, Viet Nam).* Most economies are operating conformity assessment bodies in accordance with ISO/IEC 17011, ISO/IEC 17025, and ISO/IEC Guide 65. Some consider risk-based approaches when developing assessment procedures. Viet Nam is using the seven approaches in ISO/IEC Guide 67, ranging from type testing to testing and assessment of products by a third party, and testing and calibration based on ISO/IEC CASCO standards. Mexico has adopted the following international standards and guidelines: ISO/IEC Guide 67, ISO/IEC 17000, ISO/IEC 17020, ISO/IEC 17030, ISO/IEC 17040, ISO/IEC 17043, ISO/IEC 17050-1 and ISO/IEC 17050-2.

*Hybrid system of mandatory and voluntary certification laws and practices (Chile, China, Indonesia, Malaysia, New Guinea, Russia).* Conformity assessment processes are usually determined and supervised by the government and assessments are carried out by the responsible agency or contracted out to authorized conformity assessment bodies. In some economies (Chile and China for example), third party is the preferred method. Voluntary approaches include implementation of ISO 9001 (Indonesia, New Guinea), ISO 14001, and authorization through standards bodies (Malaysia). The Russian Federal Law 184-FZ on Technical Regulations stipulates adherence to several conformity assessment principles for mandatory and voluntary rules.

*Hybrid system of Supplier Declaration of Conformance (SDoC) and third party based on risk (Australia, Canada, New Zealand, Chinese Taipei).* This approach combines measures that rely on consumers, suppliers, government agencies and voluntary standards and conformance infrastructure to ensure product safety. Australia, for example, covers products that are not regulated by specific agencies. SDoC is used for several sectors, such as electromagnetic



compatibility (EMC), for telecommunication equipment and motor vehicles. In some economies, third-party assessment is preferred because it shifts costs away from the regulators. Of course, it remains up to the regulator to choose which approach to take. Third party is also often preferred for medium to high-risk products such as electrical safety devices, medical devices, and construction products, and in sensitive sectors such as medical devices and pharmaceuticals.

***Different legislative and regulatory practices based on sector and product (Hong Kong China, Japan, the United States, Thailand).*** It is common for different government departments to take different approaches to conformity assessment. For example, in Hong Kong China, electrical product safety regulation covers the safety of all household products; an energy efficiency labeling scheme is implemented for room air conditioners, refrigerating appliances, compact fluorescent lamps, washing machines and dehumidifiers. In Japan, if a law is in place requiring the prevention of hazards and disturbances, a third-party certificate is required. Some government agencies have assigned external organizations the responsibility of administering and performing the requirements (e.g., Thailand for medical devices).

***Government authorization of conformity assessment bodies (CABs) to verify compliance and monitor the implementation of technical regulations (Peru).*** Government entities (ministries) authorize domestic or internationally accredited CABs to perform certain tasks. In other cases, they use their own laboratories for control and monitor functions, even if those laboratories are not accredited.

***No government-preferred approaches (Singapore).*** Generally, there is no preferred approach as the regulations allow SPRING (conformity assessment regulations for certification and testing of controlled goods) to be imposed as the government deems fit.

***Based on the principles of the WTO TBT Agreement and policy guidance (Australia, United States).*** The TBT Agreement and federal government guidance provides that programs under consideration should have a sound rationale and be subject to public comments before being launched. Consideration should also be given to the results of conformity assessments carried out by other agencies, and such agencies are encouraged to use relevant international standards and procedures.

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#### ***4. Do your economy's technical regulations include explicit conformity assessment requirements: Always? Usually? Occasionally? Never?***

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The difference between “usually” and “occasionally” is subjective. Why did we ask this question? It has to do with the notification requirements of the TBT Agreement. Including conformity assessment requirements in the same text as the technical regulation is acceptable; having the technical requirements and the conformity assessment requirements in separate documents is also acceptable. But when they are issued separately, it is easier to overlook the TBT requirement for notification. Our sense is that sometimes draft regulations containing primarily conformity assessment rules are not notified. There could be several reasons for this. It is important to remember that even when the requirements are in accordance with international standards, draft rules must be notified if they affect trade. Notification fulfills the key transparency requirement in the TBT Agreement so that WTO members are informed and aware of upcoming rules.

- **Always (6):** China, Indonesia, Mexico, The Philippines, Russia, Chinese Taipei.

- **Usually (8):** Canada, Chile, Hong Kong China, Korea, Malaysia, New Zealand, Thailand, Viet Nam.
- **Occasionally (5):** Australia, Japan, Papua New Guinea, Peru, the United States.
- **Never (2):** Brunei, Singapore.

***5. Do you have laws, regulations, rules or formal guidance that prescribes rules for specific products? If “yes” please provide a list of the products or sectors.***

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All economies answered this question positively. Many examples were cited such as electrical and electronic products, environmental products, consumer products, telecommunications, building equipment, automotive, medical devices, farm products, forestry, pressure equipment and processed foods.

- Australia: high risk medical products, mobile transmitters, personal protection equipment and electrical equipment. Also see Q2 in Appendix A.
- Brunei: electrical equipment, prepared foods, automotive, healthcare, medical devices pharmaceutical, rubber and wood-based products.
- Canada: electrical products, construction products, pharmaceuticals, medical equipment, wastewater systems.
- Chile: Electrical products, fish, building materials, transportation, toys, cosmetics.
- China: See Directory description of Compulsory Certification product catalogue.
- Hong Kong China: Electrical products including lamp holders, heaters and flexible cords, plugs and adaptors, MEELS for five electrical products implemented through Energy Efficiency Ordinance.
- Indonesia: Food products, electrical and electronic products, timber.
- Japan: Consumer products, electrical appliances, building and fire service equipment, industrial safety and health equipment.
- Korea: Electrical appliances, environmental, food, oil and oil alternative fuels, new and renewable sources of energy, intelligent robots.
- Malaysia: No product list was provided.
- Mexico: Electrical and electronic products, household appliances, IT equipment, energy efficiency products, industrial personal protection equipment, gas products, cosmetics, alcoholic beverages, mango, habanero chilies.
- New Zealand: Pressure equipment, cranes, electrical products, food testing products.
- Papua New Guinea: Electrical, electronic and telecommunications equipment.
- Peru: Packaged foods, tires, cables and cords, batteries, Peruvian beverages, natural gas products, hydro-biological products.
- The Philippines: electrical, electronic equipment, radio and telecommunication terminal equipment, organic products, meat and fish products, seeds, fertilizers and pesticides, petroleum products, processed foods and health products.
- Russia: No product list was provided but reference to Article 7 (contents of technical regulations) of the federal law 184-FZ, Chapter 2, was provided.

- Singapore: See answer to Question 2.
- Chinese Taipei: See answer to Question 4.
- Thailand: Medical device products, physical therapy products.
- The United States: In addition to the answer in Question 4, electrical products for use in hazardous locations, in healthcare facilities and nuclear power plants.
- Viet Nam: Decree 132/2008 covering a number of articles on quality of goods and products.

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**6. Do these conformity assessment rules cite international conformity assessment standards (such as ISO/IEC17025, ISO/IEC 17065) or international mutual recognition arrangements (such as PAC/MLA, IAF/MLA, APLAC/MRA, ILAC/MRA) or other international schemes (such as the IECEE/CB Scheme)? If yes, please list them.**

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Almost all economies indicated that some of their conformity assessment rules cite the international standards mentioned, the international MRAs, and international schemes such as the IECEE CB Scheme. Several indicated that, for certain products, the government recognizes certificates and test reports issued by IECEE-recognized NCBs or by ASEAN bodies that are signatories to ILAC and APLAC MRA. One economy indicated that its regulations state the use of international MRAs without mentioning a specific organization.

- **ISO/IEC standards.** Australia, Brunei, Canada, Chile, China, Hong Kong China, Japan, Malaysia, Mexico, New Zealand, Peru, The Philippines, Republic of Korea, Russia, Singapore, Chinese Taipei, Thailand, the United States, Viet Nam.
- **Accreditation Mutual Recognition Arrangements.** Australia, Brunei, Canada, Chile, China, Hong Kong China, Korea, Malaysia, Mexico, New Zealand, Papua New Guinea, Peru, The Philippines, Russia, the United States, Viet Nam.
- **IECEE/CB Scheme.** Australia, Canada, China, Hong Kong China, Korea, Malaysia, Mexico, New Zealand, Russia, Singapore, the United States, Viet Nam.
- Other regional groups, such as ASEAN, Brunei, The Philippines.

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**7. Please cite any recognition agreements (of conformity assessment results) with other economies (governments) or regionally that your government has entered into.**

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A number of APEC economies reported the use of private sector conformity assessment arrangements in their responses. They are not included in the information below but are in the survey responses in Appendix A.

- Australia: EU and EFTA MRA, MRA with Singapore on CA, TransTasman MRA with New Zealand, APEC-EE MRA, APEC-TEL MRA, Australia-Canada medicines GMPs.
- Brunei: ASEAN Cosmetic Directive, ASEAN Harmonized Electrical and Electronic Equipment Regulatory Regime and the APEC EE MRA (included in answer to question 8).
- Canada: APEC-TEL MRA, Telecom MRA with EU, EEA, EFTA, Switzerland, Israel, Pharmaceuticals MRA with Australia and the EU.
- Chile: APEC-EE MRA, MOUs with Australia and the United States on beef grading systems. Arrangement for Exchange of Information on Toys, Electricity and fuels test results and

certificates issued by North American and European Union Economies; recognition of agreements for exports of fishery, agriculture and cattle.

- China: Electrical and electronic equipment with New Zealand.
- Hong Kong China: New Zealand, EFTA and Chile (yet to be effective).
- Japan: EU, Singapore, The Philippines, Thailand, the United States, Chinese Taipei. Scopes are not indicated.
- Korea: APEC-TEL MRA (Canada, the United States, Singapore, Chile, Viet Nam).
- Malaysia: ASEAN MRA, other bilateral and multilateral FTAs.
- Mexico: APEC-TEL MRA (Canada, the United States), testing laboratory recognition with the United States on tires, with Canada and the United States on product safety, Telecom MRA with Canada and the United States and APEC-Toys MRA.
- New Zealand: MRA with the EU, FTA with China on electrical and electronic equipment, signatory to APEC EE MRA.
- Papua New Guinea: Signatory to APEC EE MRA.
- Peru: Agricultural products with Chile.
- The Philippines: ASEAN EEE MRA, working on implementing the ASEAN Tel MRA.
- Russia: No government agreements in the APEC region.
- Singapore: ASEAN EE MRA, APEC EE MRA, ANZSCEP with New Zealand, AS with Australia, JSEPA with Japan.
- Chinese Taipei: MRA for electrical and electronic products with Japan, New Zealand and Singapore, APEC Tel MRA Phase I with Australia, Canada, Hong Kong China, Singapore and the United States, and Phase II with Canada.
- Thailand: Not currently, but maybe in the near future with ASEAN economies.
- The United States: EU, EEA/EFTA, APEC-TEL MRA, CITEL for telecommunications equipment, Israel, Japan and Mexico for telecommunications equipment.
- Viet Nam: Various ASEAN MRAs for dental and for medical practitioners, GMPs, EEE, cosmetics, architectural and for technical services, APEC EE MRA.

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***8 . Please briefly describe any cooperative or joint work you are doing with other economies or group of economies.***

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Some respondents indicated that they cooperate with specific economies on specific products or sectors. Others cooperate with a group of economies in their own region (i.e., Russia cooperates with the Eurasian Economic Community and the United States has formal regulatory dialogue with Canada and Mexico). Several participate in the assessment activities of ISO, IEC, APLAC, IAF, ILAC PAC, APEC SCSC, and ASEAN, but did not cite joint work with other economies. Peru indicated that it receives technical assistance from Korea to implement a monitoring system for the certification of electrical and electronic products, and Korea has developed its own cooperation program to promote and develop domestic metrology, conformity assessment, and standards education with the participation of economies within and outside APEC and with regional organizations.

- Australia: Engaged in nine FTA negotiations, five bilaterals with China, Japan, Korea, India and Indonesia, and four plurilateral with the Trans-Pacific Partnership (TPP) Agreement, the Gulf Cooperation Council (GCC), the Pacific Agreement on Closer Economic Relations (PACER Plus), and the Regional Comprehensive Economic Partnership Agreement (RCEP). There are also formal regulatory dialogues with New Zealand and other economies.
- Brunei: P4 EE Sector (P4 TBT Agreement)
- Canada: ILAC, IAF, APLAC and IAAC. Cooperative accreditation arrangements with ANAB (the United States), JAS-ANZ (Australia and New Zealand), JAB (Japan), and EMA (Mexico) for QMS and EMS registrars.
- Chile: P4 EE Sector (P4 TBT Agreement), FTA negotiation with TPPs, Alianza del Pacifico on regulatory cooperation in pharmaceuticals and cosmetics, Colombia, negotiation of MRA on cosmetics, Mexico, analyzing a possible MRA on pharmaceuticals.
- China: Conformity assessment groups with the United States and ET.
- Hong Kong China: FTA partners with other economies.
- Indonesia: Participation in ASEAN activities.
- Japan: Regular meetings for information exchange with several economies, including the United States.
- Malaysia: Cooperation and joint work on FTAs and in APEC SCSC.
- Mexico: Participation in ISO/CASCO, IEC/CAB, Comisión Panamericana de Normas Técnicas (COPANT), Pacific Area Standards Congress (PASC), Foro de los Comités Nacionales de la IEC de América (FINCA) and negotiation with Saudi Arabia of MOU on technical cooperation.
- New Zealand: Participation in ILAC and APLAC and with Australia, generally. Government negotiations on FTAs.
- Papua New Guinea: Participation in joint work with APEC/APLAC proficiency testing and in the APEC Pathfinder initiative on food safety.
- Peru: Receiving technical assistance and cooperation from Korea to implement a monitoring and control system in certification of electrical and electronic products.
- The Philippines: ASEAN and APEC initiatives on harmonization of medical devices and telecommunications equipment; ASEAN consultative committees.
- Russia: Cooperation with the Eurasian Economic Community (EurAsEC).
- Republic of Korea: Participation in international and regional organizations. Developed cooperation program for metrology and conformity assessment and to promote standards education in partner economies and regional organizations (Indonesia, Peru, Viet Nam, ASCO, GSO, COPANT, PASC, ACCSQ).
- Singapore: No response provided.
- Chinese Taipei: Pharmaceutical Inspection Convention and Inspection Cooperation Scheme (PIC/S).
- Thailand: With ASEAN economies via ACCSQ-MDPWG.
- The United States: Formal regulatory dialogue with Canada and Mexico, cooperative agreements with Australia, Peru, Singapore and Chile. Finalizing TPP negotiations.

- Viet Nam: Participating in the ASEAN-ACCSQ WG on standards and MRA (WG 1) and on accreditation and CA (WG 2).

### ***9. What steps does your government undertake in an effort to implement good regulatory practices when developing conformity assessment requirements?***

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Various steps are taken. Several member economies indicated harmonization with regional and international standards, having domestic guidance referring to APEC GRP, consulting with stakeholders in drafting technical regulations, and/or requiring regulatory impact statements for new and revised legislation to ensure GRP principles are followed. Some indicated that they are taking several steps to implement GRP, such as determining the need and objectives for a regulation, doing risk assessment and hazard analysis, determining the impact on stakeholders, and consulting with stakeholders. The follow-up questionnaire (Appendix B) did not reveal any additional substantive information. It requested details on specific actions to comply with Article 5 of the TBT Agreement to support GRPs in relation to conformity assessment. Australia, Canada, Hong Kong China, Mexico, New Zealand, Chinese Taipei and Viet Nam responded, all indicating “yes” in response to all questions noting that they comply with the obligations. See Appendix B.

- Australia: Has policies to facilitate recognition of measurement standards and CA results consistent with obligations under the WTO TBT Agreement. See detail in answer to Question 2 in Appendix A.
- Brunei: Using ASEAN GRP defined in the ASEAN Policy Guidelines on Standards and CA and they are consistent with international standards.
- Canada: Practices are consistent with the TBT Agreement provisions.
- Chile: The Decree 77 embodies GRP because it establishes criteria for preparing, adopting and applying the technical regulations and conformity assessment procedures relating to those regulations in order to ensure that they do not become technical barriers to trade.
- China: Pre-survey before developing conformity assessment requirements; broad consultation during development; regular review, check and simplification of requirements.
- Hong Kong China: It has been the general practice to adopt international standards as far as possible. In formulating legislation and regulation, transparent and open consultation with stakeholders has been the practice.
- Indonesia: There is guidance on how to implement a domestic standard as a domestic regulation that refers to APEC GRP.
- Japan: There is a public comment system in place.
- Malaysia: The Malaysia Productivity Corporation leads the GRP initiative, which is under the purview of the committee that approves all technical regulations.
- Mexico: After receiving and evaluating comments from WTO members, as well as other stakeholders, the official reply and modifications, if needed, are published in the Official Journal. Each regulation requires a regulatory impact analysis (RIA) in accordance with OECD guidelines and is published for public review and comments in the Official Journal.
- New Zealand: RIA statements are required for new regulations and they are examined to ensure GRP is followed.



- Papua New Guinea: The topic will be discussed in connection with the soon-to-be-reviewed NISIT Act of 1993.
- Peru: GRP guidelines, based on APEC, are being developed in the Andean community (Bolivia, Colombia, Ecuador and Peru) and are expected to be implemented soon.
- The Philippines: General practice is to harmonize domestic standards with international standards agreed on in ASEAN and cite in regulations; consult stakeholders; and submit proposals for public review.
- Republic of Korea: Solicit comments from stakeholders before announcing new and revised CA requirements.
- Russia: The internal coordination system is well-suited to promoting compliance with TBT Agreement, including public review. Full answer in Appendix A includes recommendations on strengthening TBT-related GRP implementation.
- Singapore: Uses international standards where possible; collaborates with stakeholders.
- Chinese Taipei: Requirements are developed on the basis of risk assessment and hazard analysis and are available for public review.
- Thailand: For upcoming laws GRPs are to be initiated.
- The United States: The development of regulations follows the Administrative Procedures Act, which requires submission of public comments and that all comments are addressed. The Federal Register publishes proposed rules for public comment as well as final rules. And those are codified in the Code of Federal Regulations.
- Viet Nam: Has several steps to implement GRPs for each regulation (e.g., determining need, objectives, consultation with stakeholders, collection and analysis of comments).

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**10. Are any of these requirements in the previous question based on voluntary sector agreements and if so, are they mandated by law?**

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Some economies such as Australia, Canada, Korea, Mexico, New Zealand, The Philippines, Singapore and Thailand indicated that some conformity assessment requirements are developed on the basis of voluntary sector agreements and others, depending on the regulatory agency, are mandated by law or become mandatory when they are cited in regulations.

Other economies such as Chile, China, Hong Kong China, Malaysia, Indonesia, Peru, Russia and Viet Nam stated that they have laws that regulate mandatory and voluntary product certification. Singapore and the United States stated that none of these requirements are mandated by law.

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**11. Does your economy have mandatory conformity assessment requirements for (a) electrical installation rules, (b) photovoltaic products, and (c) medical devices-pacemakers?**

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**Electrical installation**

- Yes: Australia, Brunei, Canada, Indonesia, Mexico, The Philippines, Republic of Korea, Russia, the United States.
- No: Chile, New Zealand, Peru, Viet Nam.

**Photovoltaics**

- Yes: Australia, Chile, Japan, Mexico.
- No: Indonesia, Malaysia, New Zealand, Peru, Republic of Korea, Russia, Chinese Taipei, the United States, Viet Nam.

**Medical devices / pacemakers**

- Yes: Australia, Chile, China, Hong Kong China, Japan, Korea, Malaysia, Mexico, The Philippines, Russia, Chinese Taipei, the United States.
- No: Indonesia, New Zealand, Peru, Viet Nam.

Some economies indicated that, depending on the type of electrical equipment, electrical installations may be subject to mandatory certification or declaration of conformity. Photovoltaic equipment is not usually regulated and conformity assessment, including inspection, is mostly voluntary (with the exception of Australia for the electrical installation of PVs and Japan where a solar PV system must meet the requirements of the Building Standards Act). Conformity assessment for pacemakers is usually mandated by law requiring manufacturers to obtain licenses and to carry out product registration. Also, there is typically continuous monitoring of pacemakers by the economies' regulatory agencies.

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***12. For these rules, please indicate if (according to 5.1.1 of the TBT Agreement) suppliers of similar products in other economies have access to conformity assessment in the same manner as suppliers from your economy.***

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Almost all economies responded that domestic and foreign suppliers have the same access to the same conformity assessment processes, although processes among economies vary. The Philippines indicated that for pacemakers, there is a need to have a local distributor.

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***13. In these rules and for the two products in the previous question, please indicate if your economy recognizes Supplier's Declaration of Conformity (SDoC), only certification by a third party, or a combination of the two. Please explain.***

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Some responses did not include the products requested. For medical devices, in most of the economies third-party certification is usually required. Malaysia states that the SDoC is accepted for medical devices. Others, like Brunei, Singapore, Thailand, and Viet Nam state that there are no regulations for these products.

- Australia: See response in Appendix A.
- Canada: SDoC is not accepted.
- Chile: Only third-party certification is recognized.
- China: Only third-party certification is recognized.
- Hong Kong China: For pacemakers only third party is recognized.
- Indonesia: Conformity assessment may include all of the above.
- Japan: Please refer to [www.meti.gov.jp/english/policy/economy/consumer/pse/index/.html](http://www.meti.gov.jp/english/policy/economy/consumer/pse/index/.html)
- Korea: third-party certification is recognized for medical equipment.
- Malaysia: SDoC is accepted for medical devices.
- Mexico: SDoC is not considered for these products.



- Russia: Marks of conformity may be recognized in accordance with the government's international agreements.
- Chinese Taipei: SDoC is not recognized for pacemakers.
- The United States: SDoC is widely accepted. For electrical installations there are some requirements for third party particularly for LV equipment.

***14. Do the products above need to have an economy-wide certification mark before sale? Please explain.***

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Some of the answers did not clearly identify which products require a mark.

No certification mark is required in Japan, Malaysia, Mexico (not a domestic mark but a mark of an accredited NCB), New Zealand, Papua New Guinea, Peru, The Philippines (although a certificate of registration for pacemakers is required), Singapore, Chinese Taipei, Thailand and The United States.

A regulatory compliance mark is required in Australia (for some electrical equipment), Canada, Chile (not a domestic mark but a mark of an accredited NCB), China, Indonesia (for some electrical/electronic products), Korea (only for electrical appliances), Russia, and Viet Nam (for hazardous products).



# Appendix A. Survey Answers

This appendix documents the responses provided by each APEC member to the on-line survey. Some responses have been edited for ease of usage of terms and content.

## SURVEY QUESTIONS

1. Name, title and contact information.
2. Does your economy have a law, regulations, rules or formal guidance that specifies a general policy (not product specific) for conformity assessment? If yes, please provide the text and/or a link to it. If the text is too long for the space allowed, please provide a point of contact for follow-up purposes.
3. What are, generally and briefly, your government's preferred conformity assessment approaches? Stated another way, how would you describe, generally and briefly, your government's conformity assessment practices?
4. Do your economy's technical regulations include explicit conformity assessment requirements?
5. Does your economy have laws, regulations, rules or formal guidance that prescribes conformity assessment rules for specific products? If yes, please provide an illustrative list of the products or sectors.
6. Do these conformity assessment rules cite international conformity assessment standards (such as ISO/IEC 17025, ISO/IEC 17065) or international mutual recognition arrangements (such as PAC, IAF/MLA, APLAC, ILAC/MRA) or other international schemes (such as the IEC CB Scheme)? If yes, please list them.
7. Please cite any recognition agreements (of conformity assessment results) with other economies or regionally that your government has entered into.
8. Please briefly describe any cooperation or joint work you are participating in with other economies or group of economies.
9. What steps does your government undertake in an effort to implement Good Regulatory Practices when developing conformity assessment requirements?
10. Are any of these requirements in Question # 9 based on voluntary sector agreements and if so are they mandated by law?
11. Does your economy have mandatory conformity assessment requirements in these rules (electrical installations) and also for these two products (photovoltaic and medical equipment-pacemakers)? If yes, please provide general information of the requirements and/or a link to the regulation or rule, including a point of contact for follow-up purposes.

12. For these rules/ products, please indicate if (according to 5.1.1 of the TBT Agreement) suppliers of similar products in other economies have access to conformity assessment process in the same manner as suppliers from your economy.
13. In these rules and for these two products please indicate if your economy recognizes Supplier's Declaration of Conformity (SDoC), only certification by a 3rd party or a combination of the two? Please explain.
14. Do the products need to have an economy-wide certification mark before sale? Please explain.

## AUSTRALIA

Q2: While there is no specific law or regulation that specifies a policy for conformity assessment, the government has institutionalized good regulatory practice (GRP) in the regulatory process and the Office of Best Practice Regulation (OBPR) plays a central role in assisting governments to meet the requirements of best practice regulation. All regulatory processes are consistent with the principles of best practice regulation highlighted in the following:

- Best Practice Regulation Handbook (June 2012 edition),
- COAG Best Practice Regulation: A Guide for Ministerial Councils and National Standard Setting Bodies (COAG Guide), and
- The report on Good Regulatory Practices in APEC Member Economies -Baseline Study (November 2011).

Also, some states and territories have equivalents to the Best Practice Regulation Handbook.

Australia's regulation and conformity assessment processes operate on a risk- based system where product regulation and conformity assessment is commensurate with potential riskiness. In general, consumer products not regulated by a specific organisation are managed under the Australian Consumer Law (ACL) and include a harmonized system of domestic regulations with government agencies enforcing these regulations. Please refer to the following website for further information: [http://www.consumerlaw.gov.au/content/Content.aspx?doc=the\\_acl.htm](http://www.consumerlaw.gov.au/content/Content.aspx?doc=the_acl.htm).

A number of product sectors are also regulated and monitored by specific authorities. For example, the Australian Communications and Media Authority (ACMA), is vested under the Radiocommunications Act 1992 with the statutory responsibility to manage the use of the radiofrequency spectrum. The ACMA's electromagnetic compatibility (EMC) regulatory arrangements set out compliance requirements for electrical and electronic products to minimize interference to the radiofrequency spectrum. The Australian EMC Regulatory Arrangements have three levels which correspond to risk: Level 1 applies to products whose interfering emissions have a low impact on devices using the radiofrequency spectrum, covering products such as electric blankets and electric jugs. Level 2 applies to products whose interfering emissions would have a higher impact on the radiofrequency spectrum. Examples of Level 2 products are a microprocessor or other clocked digital device and arc welding equipment. Level 3 applies only to products whose interfering emissions have the highest risk of serious impact on devices using the radiofrequency spectrum. For example, Level 3 covers industrial scientific and medical products under the EMC standard, CISPR 11.

Similarly, the Therapeutic Goods Administration (TGA) administers the Therapeutic Goods Act 1989, which provides a framework for a risk management approach allowing consumers to have timely access to safe therapeutic goods. The regulatory framework adopts a classification system to categorize medical devices into 5 classes according to the level of risk posed (Class I, Class IIa, Class IIb, Class III and Active Implantable Medical Devices – AIMD). The classification of a medical device determines the conformity assessment procedure(s) a manufacturer can choose to demonstrate that the device conforms to the particular requirements. For example, for the lowest risk medical device, (Class I medical devices and Class I in-vitro diagnostic medical devices (IVDs)), conformity assessment may take the form of self-certification or self-declaration by the manufacturer, while for high risk medical devices,

manufacturers may choose to implement a full quality management system taking into account regulatory requirements and final inspection processes. Manufacturers of high-risk medical devices may alternatively choose to undergo type testing for their devices. In such cases, a representative sample has to be examined by the TGA (or other appropriate body) to determine if the design of the type satisfies the essential principles through testing. In addition, overseas manufacturers of certain high-risk medical devices must hold a conformity assessment certificate issued by the TGA prior to supply of the devices in Australia, regardless of any certification that they may hold from other regulatory authorities. Please see the online publication TGA's risk management approach to the regulation of therapeutic goods (September 2011) for more information.

At a state level, the Electrical Regulatory Authorities Council (ERAC) aims to coordinate a harmonized Electrical Equipment Safety System (EESS). This system requires risk-based classification of equipment into three levels (high, medium and low risk). Under the EESS, all in-scope electrical equipment must be electrically safe and meet the relevant standards. Low risk products require a self-declaration by a 'Responsible Supplier. Level 2 risk electrical equipment requires a Responsible Supplier to keep a compliance folder recording evidence that must include test reports completed by an approved testing entity or a suitably qualified person. Lastly, the evidence of compliance for high-risk equipment is a valid Certificate of Conformity. Further information can be found at the Safework Australia site:  
<http://www.safeworkaustralia.gov.au/sites/swa/model-whs-laws/model-whs-act/pages/model>.

Q3: The Australian system is a risk-based system where regulation and conformity assessment is associated with potential risk of the product. The government's approach combines measures that rely on consumers, suppliers, government agencies and the standards and conformance infrastructure, working together to ensure products work safely. The ACL provides a 'catch all' and specifies a safety and enforcement framework for products that are not subject to particular standards or technical regulations, and are not regulated by a specific agency. However, as discussed in Q2, a number of riskier products are regulated by specific authorities. The new harmonized Electrical Equipment Safety System (EESS) classifies electrical products into low, medium and high risk. The system dictates proportionate conformity assessment at each level. Similarly, as discussed in Q2, the TGA provides a framework for a risk management approach to the conformity assessment of therapeutic goods.

Furthermore, the government sets policies consistent with Australia's obligations under the TBT Agreement and bilateral Free Trade Agreements (FTAs).

Q4: Occasionally, a regulator will specify the relevant conformity assessment requirements. This will be especially pertinent when the product could impose a significant adverse risk if it fails to comply with the principal standard or technical regulation.

- At the Commonwealth level, the Department of Families, Community Services and Indigenous Affairs, has a Quality Strategy which includes a quality assurance system that passed into law in 2002. This requires services funded under the Disability Services Act 1986 (Cth) to be independently assessed and certified as complying with the Disability Services Standards. Audits against the Disability Services Standards are conducted by independent third party certification bodies. These certification bodies are accredited to perform audits against the Disability Services Standards by the Joint Accreditation System of Australia and New Zealand (JAS-ANZ).

- The TGA performs third-party conformity assessment for high risk medical products. In the case of some manufacturers and IVDs in several risk classes the manufacturer must have a TGA Conformity Assessment Certificate.
- The Australian Communications and Media Authority (ACMA), as specified in the Radiocommunications (Compliance Labeling – Electromagnetic Radiation) Notice 2003, imposes requirements on suppliers of mobile transmitters to ensure such devices comply with the Radiocommunications (Electromagnetic Radiation – Human Exposure) Standard 2003 and label their product with a compliance mark. The notice includes three levels; level 1, level 2 and level 3 and requires that testing of level 3 products will be restricted to laboratories accredited by the National Association of Testing Authorities, Australia (NATA), or a laboratory accredited by a body with which NATA has a mutual recognition agreement.
- At the state level, the Electrical Equipment Safety System (EESS) will result in changes to Electrical Safety Act 2002 and the Electrical Safety Regulation 2002. In support of the EESS, the Electrical Regulatory Authorities Council (ERAC) approved and released the Equipment Safety Rules, also known as ‘the scheme rules’, in November 2012, which can be viewed at [www.erac.gov.au](http://www.erac.gov.au)(<http://www.erac.gov.au/>).

See further detail at Q2.

Q5: Australia regulates high risk medical products, mobile transmitters, pressure equipment, cranes, personal protection equipment and electrical equipment. Also see Q2.

Q6: Some of the specific schemes that are established under Commonwealth and state regulations, like those above in Q4, utilize ISO/IEC Guide 65. The EESS also makes use of both the International Accreditation Forum (IAF) MLA and International Laboratory Accreditation Cooperation (ILAC) MRA.

Q7: Australia is a signatory to a number of Mutual Recognition Agreements and Arrangements listed below:

- Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings, between Australia and the European Community
- European Free Trade Association Mutual Recognition Agreement (EFTA-MRA) with Norway, Iceland and Liechtenstein
- Australia-Singapore Mutual Recognition Agreement on Conformity Assessment (Singapore-MRA)
- Trans-Tasman Mutual Recognition Arrangement (TTMRA), which facilitates trade with New Zealand
- APEC Mutual Recognition Arrangement on Conformity Assessment of Electrical and Electronic Equipment (APEC Electrical MRA)
- APEC Tel Mutual Recognition Arrangement (APEC-Tel MRA) on conformity assessment of telecommunications equipment (APEC Tel MRA)

- Australia-Canada Mutual Recognition Agreement on Medicines Good Manufacturing Practice Inspection and Batch Certification.

Furthermore, there are mutual recognition arrangements (MRAs) in the voluntary sector with international conformity assessment bodies.

Standards Australia is the peak standards writing body and Australia's representative in international and regional for a such as the ISO, IEC and Pacific Area Standards Congress (PASC). More information can be found at [www.standards.org.au](http://www.standards.org.au).

The National Association of Testing Authorities (NATA) is recognised by the government as the domestic authority for the accreditation of laboratories conducting tests and measurements in all technical fields and as a peak authority for the accreditation of inspection bodies. NATA is a signatory to the global ILAC Arrangement and the Asia Pacific Laboratory Accreditation Cooperation (APLAC) regional MRA. NATA also maintains a bilateral arrangement with the European cooperation on Accreditation (EA) with respect to testing, calibration and inspection. NATA's MRAs are crucial to the recognition of Australian testing, inspection and calibration data overseas, and to the acceptance of Australian goods in foreign markets. The Joint Accreditation System of Australia and New Zealand (JAS-ANZ) plays a key role in establishing international arrangements with other economies to accept one another's certificates and inspection reports. From a voluntary perspective, JAS-ANZ is a signatory to the IAF MLA for the scope of ISO 9001, ISO 14001 and Product Certification. JAS-ANZ is also a signatory to the APLAC MRA and ILAC MRA for the scope of Inspection, and is an active participant in Pacific Accreditation Cooperation (PAC). For more information please see the NATA website [www.nata.com.au](http://www.nata.com.au); and the JAS-ANZ website; [www.jas-anz.com.au](http://www.jas-anz.com.au).

Q8: Please see Q7 above.

In addition to joint work related to mutual recognition, Australia has six FTAs currently in force with New Zealand, Singapore, Thailand, the United States, Chile and ASEAN. All of Australia's existing FTAs have TBT Chapters which provide for relevant joint work and cooperation with other economies. Australia is currently engaged in nine FTA negotiations - five bilateral FTA negotiations: China, Japan, Korea, India and Indonesia; and four plurilateral FTA negotiations: the TPP, the GCC, the PACER Plus, and the Regional Comprehensive Economic Partnership Agreement (RCEP).

The Australian Government also has formal regulatory dialogues with New Zealand, undertakes numerous initiatives with other APEC economies and participates in the discussions pertaining to the WTO TBT Agreement.

Q9: Please see Q2 above.

Q10: The government recognizes voluntary sector arrangements, in that the mutual recognition arrangements of JAS-ANZ and NATA are utilized quite frequently in regulation. Regulators that either mandate or recognize accreditation by NATA and MRA partner accredited laboratories include the following.

- ACMA (Commonwealth) - for radio communications, electromagnetic compatibility and telecommunications
- ACCC (Commonwealth) - for the products that they directly regulate



- Environmental Department (Commonwealth) for oil quality
- Electrical safety regulators (state) - for domestic appliances and accessories
- DSD (Commonwealth) - for equipment security evaluations
- Gaming regulators (State) - for ICT testing of gaming equipment. Industry sectors such as food and construction utilize voluntary accreditation systems (testing and certification) without the impost of regulatory requirements.

Industry sectors such as food and construction utilise accreditation systems (testing and certification) without the impost of regulatory requirements.

Q11:

A. Photovoltaics/Electrical installation: Yes.

B. Medical equipment: Australia has mandatory conformity assessment requirements for all medical devices including specific requirements for active implantable medical devices (AIMDs) such as pacemakers.

A. In Australia, electrical installers must be accredited by the Clean Energy Council and must demonstrate competence in design and/or installation of stand-alone and /or grid connected solar photovoltaic power systems to qualify for associated rebates. Low voltage installations must be installed by licensed electrical workers. Furthermore, PV installations themselves are to comply with AS/NZS 5033 and AS/NZS 3000 (The Wiring Rules). The wiring rules are called up in legislation. Grid connected inverters must comply with AS4777 and AS/NZS 5033 requires PV panels to comply with the relevant IEC standard. Electrical safety, including equipment safety, in Australia and New Zealand is regulated by each Australian state and territory and New Zealand separately. The Electrical Regulatory Authorities Council (ERAC) coordinates a harmonized electrical equipment safety system. An appropriate point for contact for follow up questions on electrical installation and photovoltaics is

Leigh Richmond Electrical Safety Office of Fair and Safe Work Queensland Ph: +61 7 340 43592 [leigh.richmond@justice.qld.gov.au](mailto:leigh.richmond@justice.qld.gov.au);

B. The current Australian regulatory framework for medical devices was introduced in 2002. This regulatory framework is based on the Global Harmonisation Taskforce (GHTF) principles of medical device regulation. The Therapeutic Goods Administration (TGA; <http://www.tga.gov.au/>) - which is part of the Australian Government Department of Health and Ageing, is tasked with administering the regulatory framework for all therapeutic goods including medical devices. The regulatory requirements are set out within the Australian Therapeutic Goods Act 1989 and the Therapeutic Goods (Medical Devices) Regulations 2002. Pacemakers are classed as Active Implantable Medical Devices (AIMDs) in Australia and are considered to be in the highest risk class of medical devices. Pacemakers must undergo the conformity assessment procedure specified for highest risk medical devices. Further guidance on the conformity assessment pathways applicable to pacemakers can be found with the Australian Regulatory Guidelines for Medical Devices (ARGMD) which can be accessed on the TGA website at: <http://www.tga.gov.au/industry/devices-argmd.htm>. In particular see Sections 5-7 and Section 13. The appropriate contact for follow-up purposes is:

Andrea Kunca Office of Devices Authorisation | Marketing Authorisation Group Therapeutics  
Goods Administration Tel: +61 2 6232 8793 Mob: +61 402 754 776  
[Andrea.Kunca@tga.gov.au](mailto:Andrea.Kunca@tga.gov.au);

Q12: The regulations and rules are consistent with 5.1.1 of the TBT Agreement. The conformity assessment process grants access to suppliers, of like products originating in other economies, that is no less favourable than access accorded to suppliers of domestic products.

A. In the electrical and photovoltaics sector, grid connected PV modules imported into Australia shall comply with either IEC61730 Class A and either IEC61215 or IEC61646. PV modules are deemed Class 1 (earthed) in Australia.

B. The Australian regulatory framework for medical devices is based on the Global Harmonisation Taskforce (GHTF) principles of medical device regulation. Other economies that have also adopted regulatory frameworks based on GHTF principles of regulation include the European Union and Canada. A number of other economies (for example, the Association of South East Asian Nations) are looking to introduce regulatory frameworks based on these GHTF principles of regulation.

Q13:

A. Under the new Electrical Equipment Safety System (EESS) grid connected inverters for PV modules are considered Level 1 (Low Risk) products and therefore are not required to be registered on the domestic EESS database, however they must meet as a minimum, requirements listed in AS3820 and any other standards applicable for this class of product.

B. Manufacturers of all medical devices must complete an Australian Declaration of Conformity prior to supply of the device in Australia. As part of the conformity assessment procedures, the manufacturer of a medical device is required to make a declaration of conformity which declares that the device complies with:

- The applicable provisions of the essential principles of safety and performance;
- The classification rules;
- An appropriate conformity assessment procedure.

Templates for an Australian Declaration of Conformity - including templates applicable to AIMDs such as pacemakers - can be accessed through the TGA website at <http://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm>

For pacemakers and other AIMDs, the TGA accepts the following forms of conformity assessment certification:

- TGA Conformity Assessment Certificates issued by the TGA—this is mandatory for some manufacturers
- EC certificates issued by an EU Notified Body under the EU Active Implantable Medical Devices Directive 90/385/EEC (AIMDD)
- Some manufacturers are required to obtain a TGA Conformity Assessment Certificate.

Manufacturers that wish to supply an AIMD in Australia using an EC certificate as conformity assessment evidence will be subject to Australian pre-market regulatory review in the form of

an Application Audit. Further information on these processes is available in the Australian Regulatory Guidelines for Medical Devices (ARGMD) which can be accessed on the TGA website at: <http://www.tga.gov.au/industry/devices-argmd.htm>. In particular see Section 5 and Section 11.

Q14:

A. Under the new Electrical Equipment Safety System (EESS) if products are in-scope electrical equipment they will be required to have the Regulatory Compliance Mark (RCM). The RCM is a graphic symbol indicating a supplier's claim that a product meets applicable regulatory requirements. Provided the conditions for its use are met, electrical, EMC and radio communication regulators will accept the RCM as the supplier's claim of compliance, avoiding the need to have a different mark for each regulator. For more information please see <http://rcm-mark.com.au>;

B. There is no requirement in Australia for a medical device to have a "domestic certification mark" before sale. However, all medical devices (unless they are specifically exempt) must be included in the Australian Register of Therapeutic Goods (ARTG) (<http://www.tga.gov.au/industry/artg.htm>) before they can be lawfully supplied in Australia.

**BRUNEI DARUSSALAM**

Q2: CA requirements are consistent with WTO TBT and the ASEAN Policy Guideline on standards and conformance.

Q3: CA practices through alignment with international practices, where applicable.

Q4: Always. For example, where testing cannot be done locally, BN accepts test reports from internationally accredited laboratories.

Q5: Agro-based products (prepared food), automotive, healthcare (cosmetics, medical devices, pharmaceuticals, medicines and health supplements), electrical and electronic equipment, rubber and wood-based products.

Q6: Yes. Also, recognize test reports issued by accredited laboratories by NABs in ASEAN that are signatories to ILAC and APLAC MRA.

Q7: There is an agreement with Singapore in using their accredited laboratories for testing and accepting the test results. Also, with ASEAN Cosmetic Directive and ASEAN Harmonized Electrical and Electronic Equipment Regulatory Regime (AHEER).

Q8: P4 EE Sector (P4 TBT Agreement) and APEC EEMRA ( Parts 1, 2 and 3).

Q9: Using ASEAN GRP that are defined in the ASEAN Policy Guideline on Standards and Conformance, to work in the areas related to technical regulations and CA to promote the integration in various operations. Steps include: determining the need, objectives, stakeholder impact, consultation with stakeholders, analyzing and processing information and developing regulatory impact statements (RIS) for draft and implemented regulations.

Q10-Q14: For these sectors, international practices, if any, are accepted if there are international standards associated with them.

## CANADA

Q2. In sectors subject to third-party conformity assessment, many Canadian regulatory authorities rely on conformity assessment bodies accredited by the Standards Council of Canada (SCC). The SCC's accreditation criteria are based on ISO/IEC standards and include additional requirements to fulfill the needs of Canadian regulatory authorities (see Certification Body Accreditation Program Handbook – Conditions and Procedures for the Accreditation of Bodies Certifying Products, Processes and Services (CAN-P-1501A) at <http://www.scc.ca/en/about-scc/publications/criteria-and-procedures/can-p-1501a-certification-body-accreditation-program>).

The Standards Council of Canada (SCC) is Canada's domestic accreditation body. It accredits testing and calibration laboratories, medical laboratories, inspection bodies, greenhouse-gas verifiers and validators, and organizations that develop standards. SCC also accredits organizations that certify persons, as well as those that certify conformity of products, processes, systems and services. Additionally, SCC is the only monitoring authority in Canada that grants recognition to the OECD Good Laboratory Practice (GLP) program. <http://www.scc.ca/en/accreditation>

Q3. Canada relies on a variety of tools to ensure compliance with technical regulations, depending on a number of factors, including risks and the particular characteristics of the sector.

Canada uses suppliers' declaration of conformity (SDoC) for motor vehicles, electromagnetic compatibility and some telecommunication products. SDoC typically involves significant government costs related to enforcement and post-market surveillance. Although manufacturers must usually still bear costs associated with testing their products to ensure they conform with applicable requirements, these costs can be lower since manufacturers can choose where to test the products (e.g. in-house, if they have the facilities).

Third-party conformity assessment (3PCA) is typically used in areas in which products pose a medium to high risk to health or safety, such as electrical safety, medical devices and construction products. 3PCA provides assurance that products conform to applicable requirements before products can be placed on the market or used. 3PCA is also often preferred in sectors in which there are some or many relatively small manufacturers and where a long and well-established reputation for high quality and safety is not considered necessary to do business.

In some sensitive sectors where risks are considered high, such as pharmaceuticals, Canadian regulatory authorities are directly responsible for conformity assessment and require approval of a product.

4. Conformity assessment procedures are normally specified in Canadian technical regulations. We are not aware of any example in which this is not the case. For a specific example of conformity assessment procedures specified in a Canadian technical regulation, see Environment Canada's regulations on PCB: <http://laws-lois.justice.gc.ca/eng/regulations/SOR-2008-273/section-1-20111208.html>. Other examples are provided in our response to question 11.

5. Yes, conformity assessment procedures are normally specified in Canadian technical regulations. For an illustrative list of conformity assessment procedures used for specific products or sectors, please see response to question 3. For a specific example of conformity assessment procedures specified in a Canadian technical regulation, see the Wastewater Systems Effluent Regulations from Canada's Fisheries Act:

<http://www.canlii.ca/eliisa/highlight.do?text=ILAC&language=en&searchTitle=Search+all+Ca nLII+Databases&path=/en/ca/laws/regu/sor-2012-139/latest/sor-2012-139.html>

6. In sectors subject to third-party conformity assessment, Canadian regulatory authorities typically rely on conformity assessment bodies accredited by the SCC, whose accreditation criteria are based, partly, on ISO/IEC standards. The SCC is signatory to the ILAC/MRA, the IAF/MLA, the Inter-American Accreditation Cooperation (IAAC) MLA and to APLAC and recognizes the competence of CABs accredited by other accreditation bodies (ABs) that are signatories to the ILAC/MRA, the IAF/MLA, the IAAC MLA and to APLAC. Thus, when the SCC accredits a CAB, it will recognize the accreditation work conducted by any other AB which is a signatory to the afore-mentioned arrangements and which has already accredited that CAB.

Some Canadian regulatory authorities also directly recognize CABs accredited by signatories to the ILAC/MRA and/or the IAF/MLA. For example, the Wastewater Systems Effluent Regulations from Canada's Fisheries Act:

<http://www.canlii.ca/eliisa/highlight.do?text=ILAC&language=en&searchTitle=Search+all+Ca nLII+Databases&path=/en/ca/laws/regu/sor-2012-139/latest/sor-2012-139.html>

A determination referred to in subsection 10(4) or (5) or 11(2) or (3), paragraph 34(1)(a) or (b) or (4)(a) and any determination necessary to make that determination — other than the determination of pH of water necessary to make the determination referred to in subsection 34(3) — must be made

- (a) by a laboratory
  - (i) that is accredited under the International Organization for Standardization standard ISO/IEC 17025:2005 entitled General requirements for the competence of testing and calibration laboratories, as amended from time to time, by an accrediting body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement, and
  - (ii) whose accreditation includes the analytical method used to make the determination; or
- (b) by a laboratory
  - (i) that is accredited under the Environment Quality Act, R.S.Q., c. Q-2, as amended from time to time, by an accreditation body that is recognized in accordance with that Act, and
  - (ii) whose accreditation includes the analytical method used to make the determination. (...)

7. Canada is party to a number of multilateral mutual recognition agreements (MRAs) on conformity assessment. It has negotiated a number of MRAs to facilitate recognition of foreign conformity assessment procedures. The MRAs have been successfully implemented in sectors such as telecommunications (e.g. APEC TEL MRA, U.S., Mexico, EU, EEA EFTA, Switzerland, Israel) and pharmaceuticals (EU, Australia). However, the multi-sector MRAs have not been implemented in some of the other sectors as the necessary confidence building exercises could not be completed.

8. The SCC participates in the following voluntary arrangements between accreditation bodies:

- International Accreditation Forum (IAF)- mutual recognition of certificates for Quality Management Systems (QMS), Environmental Managements Systems (EMS) and product certification;
- International Laboratory Accreditation Cooperation (ILAC)- Recognition of testing and calibration results of accredited laboratories; (includes ILAC MoU with IEC and IEC Conformity Assessment Schemes).
- Asia Pacific Laboratory Cooperation (APLAC) - Recognition of testing and calibration results of accredited laboratories
- Inter-American Accreditation Cooperation (IAAC) – Recognition of testing and calibration results of accredited laboratories, recognition of QMS certificates, recognition of Environmental Management System certification bodies and product certification bodies

The SCC has also entered into cooperative accreditation arrangements with ANAB (United States), JAS-ANZ (Australia & New Zealand), JAB (Japan), and EMA (Mexico) for QMS and EMS registrars.

9. The Appendix of the new Canadian Cabinet Directive on Regulatory Management establishes the responsibility of departments and agencies to seek advice and comply with Canada's international trade obligations. This appendix notably draws attention to obligations regarding conformity assessment procedures contained in international agreements to which Canada is a party, including the World Trade Organization (WTO) Agreement on Technical Barriers to Trade, the WTO Agreement on the Application of Sanitary and Phytosanitary Measures, and Chapter Seven ("Sanitary and Phytosanitary Measures") and Chapter Nine ("Technical Barriers to Trade") of the North American Free Trade Agreement. In particular, with respect to conformity assessment procedures that may affect trade, departments and agencies are to:

- Consider accepting as equivalent the conformity assessment procedures of other economies, even if different, provided they achieve an equivalent level of assurance of conformity with domestic technical regulations and standards;
- Ensure that conformity assessment procedures treat products from one jurisdiction no less favourably than like products from other jurisdictions;
- Use available international standards, guidelines, and recommendations as a basis for conformity assessment procedures where they achieve the intended regulatory objective;
- Treat regulatees and products from one jurisdiction no less favourably than those from other jurisdictions when assessing conformity to technical regulatory requirements, providing they are in comparable situations;
- Have in place a process to review complaints concerning conformity assessment procedures and must take corrective action when justified; and
- Publish proposals for new or changed conformity assessment procedures that may affect international trade for a comment period of at least 75 days and take into account the comments received.

10. While there are no obligations for federal departments to reference these voluntary sector agreements in their regulations, they are encouraged to do so when possible. The Standards Council of Canada notably encourages federal departments to reference these voluntary sector



agreements in their regulations. Please consult the answer to question 6 for examples of Canadian federal regulators making use of these sector agreements.

11. Yes, Canadian electrical installation rules include mandatory conformity assessment requirements.

The Canadian Electrical Code (CEC) is developed by the Canadian Standards Association (CSA). Part I of the CEC (CSA C22.1) is the safety standard that applies to the installation and maintenance of electrical equipment in Canada. CEC, Part I, is published on a 3 year-cycle. The most recent edition was published in 2012. The CEC, Part II is comprised of various product standards pertaining to the electrical safety of electrical equipment and installations. The CEC, Part I requires that products comply with these product standards in order to be installed. The product standards are Canadian standards, which may be Canada-specific, regionally harmonized, or international standards adopted with or without domestic differences. Each product standard in the CEC, Part II must be reviewed every 5 years, and the list of standards in CEC, Part II is continuously updated accordingly.

Canadian regulatory authorities require that electrical equipment used in electrical installations within their jurisdiction be “approved” for the specific purpose for which it is to be employed. Electrical equipment is considered “approved” if it has been certified by a certification organization accredited by the SCC in accordance with the requirements of CSA standards. To put it more simply, products must be certified as conforming to the relevant CEC, Part II standard in order to be approved for installation in Canada in accordance with CEC, Part I.

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12. Electrical installation rules: Yes, Canadian and foreign suppliers must have their electrical products certified by a certification organization accredited by the SCC.

13. Electrical installation rules: Canada relies on certification by a certification organization accredited by the SCC. SDoC is not accepted.

Electrical installation rules: Yes and no: Electrical products must be certified and bear the certification mark of a certification organization accredited by the SCC in order to be approved for sale in Canada. Accredited certification organizations are required to register, protect and control their certification marks. Thus, the certification marks belong to the certification organizations. These marks are not “marks” in the sense of the EU’s CE mark.



## CHILE

Q2: We have a Decree (Decree 77 – Ministry of Economy), which establishes requirements for the preparation, adoption and application of technical regulations and conformity assessment procedures. The objective of this Decree is to ensure the fulfillment of the obligations derived from WTO/TBT Agreement and related bilateral or regional agreements on the preparation, adoption and application of technical regulations and the respective conformity assessment procedures. The Decree establishes criteria for preparing, adopting and applying the technical regulations and conformity assessment procedures relating to those regulations in order to ensure that they do not become unnecessary technical barriers to trade. There is available an English version of this Decree:

<http://www.reglamentostecnicos.cl/OtroDocumento/Contenido/28>

Q3: For example, Food Health Regulations Supreme Decree No. 977/96; Regulations of Constructions, Transport and Telecommunications, Organic products, etc.

Q4: Usually. For example, Food Health Regulations Supreme Decree No. 977/96; Regulations of Constructions, Transport and Telecommunications, Organic products, etc.

Q5: Yes. Chile performs third party conformity assessment, except a few cases.

Some examples:

- Electrical Products and fuels
- Fishing
- Building Materials
- Transport
- Piping system for domestic hot and cold water installations
- Noise emissions levels
- Toys
- Cosmetics products

Q6: Yes. For example, the REGULATION FOR THE CERTIFICATION OF ELECTRICAL PRODUCTS AND FUELS (Decree 298, Ministry of Economy): ILAC/MLA.

Q7: In the area of mandatory technical regulations, Chile participates in a number of recognition arrangements, including Part I of the APEC MRA on Conformity Assessment of Electrical and Electronic Equipment (EEMRA) and the Arrangement for Exchange of Information in Toys Safety.

The Superintendence of Electricity and Fuels recognizes test results and certification issues by organizations in a number of North American and European economies, and there are recognition agreements pertaining to exports of Chilean fishery, agriculture and cattle product into selected trade partners. Chile has signed 2 Memorandum of Understanding (with Australia and United States), where Chile recognizes the beef grading of Australia and with United States, the agreement recognizes each other's' grading systems.

Q8: P4 EE Sector (P4 TBT Agreement.) Negotiation of Free Trade Agreements: Trans Pacific Partnership (TPP); Alianza del Pacífico. In Alianza del Pacífico, we are working on regulatory cooperation in pharmaceuticals and cosmetics products. Colombia: Negotiation of MRA of

cosmetics products. Mexico: We are analyzing the possibility to negotiate a MRA in pharmaceuticals products.

Q9: The Decree 77 (REQUIREMENTS FOR THE PREPARATION, ADOPTION AND APPLICATION OF TECHNICAL REGULATIONS AND CONFORMITY ASSESSMENT PROCEDURES) is a Decree of GRP, because it establishes criteria for preparing, adopting and applying the technical regulations and conformity assessment procedures relating to those regulations in order to ensure that they do not become unnecessary technical barriers to trade.

Q10: The Decree 77 is a mandatory regulation; all the ministries and regulatory bodies have to comply with the obligations set in the Decree.

Q11: There is a Regulation for medical devices, but for specifically “pacemakers”, there is not an obligation of a “sanitary registration”.

In regard to Electrical installation, there are not obligations of conformity assessment procedures, there is a project, but it is not ready yet. There is a Chilean standard, NCH Elec. 4/2003, Standard low voltage installations, but it not requires certification, and the Superintendence of Electricity and Fuel makes the surveillance. In regard to Photovoltaic systems, we are implementing the certification, i.e., panels, inverters and bidirectional meters; we are developing the draft protocols for public consultations. All the related regulations are under the Law 20.571, Payment of Electrical Tariffs Residential Generating, Ministry of Energy.

Q12: Yes, we do. For Electrical installation rule and Photovoltaic systems, we are considering the certification trough domestic bodies and the recognition of origin certification.

Q13: For Electrical installation rule and Photovoltaic systems, we are considering only the certification by a 3rd party.

Q14: The certification has to be issued by an authorized Certifying Body, not a specific mark.

## CHINA

Q2: Regulations of the People's Republic of China on Certification and Accreditation. Please find the text on the website of CNCA ([www.cnca.gov.cn](http://www.cnca.gov.cn))

Q3: Combination of compulsory certification and voluntary certification.

Q4: Always. All the CCC rules can be seen as technical regulations including explicit conformity assessment requirement.

Q5: Directory Description and Define Table of Compulsory Certification product catalogue (<http://www.cnca.gov.cn/cnca/rdht/qzxcprz/qzscpzegg/720996.shtml>);

Q6: Yes, China's CA standards are mostly based on international standards including ISO/IEC17025, ISO/IEC17065, China's accreditation body CNAS are members of PAC, IAF/MLA, APLAC, ILAC/MRA). CCC system accepts IECEE/CB testing reports.

Q7: IECEE\_CB scheme. CCIC has signed agreement with UL. CNAS has signed agreement with PAC/IAF/ILAC.

Q8: EU-China conformity assessment working group. China-US conformity assessment working group.

Q9: 1. Pre survey before initiating the development of CA requirements. 2. Broad consultation while developing CA requirements. 3. Regular review of existing CA requirements. 4. Regular check and simplification of existing CA requirements.

Q10: There is specific law to mandate our government to regulate mandatory and voluntary production certification, and the government does regulate effectively. For voluntary certification, the certification body should first file with CNCA the specific certification implementation rules before conducting relevant certification activities. As for mandatory certification, in-depth pre-feasibility study, tight process tracking and strict post surveillance are routinely performed to ensure the certification catalogue and rules are scientific and reasonable enough to ensure that certified products conform.

Q11: Medical equipment-pacemakers are included in China Compulsory Certification product catalogue. The requirements please see Directory description and define table of CCC certification (<http://www.cnca.gov.cn/cnca/rdht/qzxcprz/qzscpzegg/720996.shtml>);

Q12: Yes. In China, for precuts requiring mandatory certification, there is unified product catalogue ("catalogue" hereinafter), unified mandatory technical regulations, standards and conformity assessment procedures, unified certification mark and unified fee chart. The conformity assessment process is the same for both domestic and foreign enterprise.

Q13: We only recognize certification by 3rd party.

Q14: According to Article 28 of the Regulation of the People's Republic of China on Certification and Accreditation: Such products may be released from the manufacturer, marketed, imported or used for any commercial purposes only after they are certified and have certification mark displayed (<http://www.cnca.gov.cn/cnca/rdht/qzxcprz/flfg/72306.shtml>);

## HONG KONG CHINA

Q2: There is no central standards body. The policy is to adopt international standards as far as possible but not using standards to dictate market development or protecting industry sectors. Formulating legislation is a transparent and open process.

Q3: It depends. The Electrical Products (Safety) Regulation covers safety of household electrical products and recognizes CB certificates of compliance or endorses such which are issued by organizations accredited by the Hong Kong Accreditation Service (HKAS) or those issued by organizations with which HKAS has MRAs or SDoC by manufacturers substantiated by test reports, etc. See [www.emsd.gov.hk/emsd/eng/pps/pub\\_gngreg01.shtml](http://www.emsd.gov.hk/emsd/eng/pps/pub_gngreg01.shtml).

Also, the Mandatory Energy Efficiency Labeling Scheme (MEELS) is implemented for certain consumer products. See

[www.energylabel.emsd.gov.hk/en/mainpage.html](http://www.energylabel.emsd.gov.hk/en/mainpage.html)

Q4: Usually. Different regulatory departments may formulate different CA requirements to suit their needs. For example, domestic electrical products are to be certified to IEC60335-1 and -2.

Q5: If CA rules are necessary to be set up, the authorities would develop laws regulations and Code of Good Practice. See details in answer to Q 3.

Q6: Yes. ILAC/MRA and IECEE CB Scheme. ISO and IEC standards where applicable are adopted for testing products under the MEELS.

Q7: HKAS is a member and signatory of IAF, ILAC, PAC and APLAC. Electrical products shall be tested to relevant IEC or domestic standards by a test laboratory accredited by HKAS or by others under the ILAC/MRA. Similarly, with energy performance of prescribed products under the MEELS.

Q8: Actively participates in WTO/TBT discussions. Have entered into FTAs with other economies to enhance communication and cooperation in technical barriers to trade.

Q9: The general practice is to adopt international standards as far as possible. Authorities use standards as and when necessary and avoid the position where the setting of standards dictates market development or to protect certain industry sectors. Transparent and open consultation with stakeholders has been the practice. Both standards and conformity assessment requirements for electrical products are designed and tested to conform to respective international standards.

Q10: The examples in Q9 above are mandated by law or regulation. In addition, under the MEELS, the importers or domestic suppliers shall comply with the CA requirements.

Q11: For medical equipment-pacemakers, HKC has implemented a Class License for Medical Implant Communication System (MICS). See [www.coms-auth.hk/filemanager/common/licensing/Medical\\_Impact\\_CS\\_Class\\_License\\_\(Eng\).pdf](http://www.coms-auth.hk/filemanager/common/licensing/Medical_Impact_CS_Class_License_(Eng).pdf)

Mandatory approval is not imposed as not to hinder patients with the freedom of travel. The Office of Communications Authority (OFCA) operates the Hong Kong Telecommunications Equipment Evaluation and Certification Scheme. Under the Scheme, suppliers of MICS may

apply on a voluntary basis for equipment certification with HKCA. See [www.ofca.gov.hk/filemanager/ofca/en/content\\_401/hkca1052.pdf](http://www.ofca.gov.hk/filemanager/ofca/en/content_401/hkca1052.pdf)

Q12: There is no difference between local and other suppliers of pacemakers.

Q13: For pacemakers, SDoC is not acceptable. Only 3rd party by a recognized CB.

Q14: There is no need to have a certification mark before sale for pacemakers. If the product is type-approved by a CB, the CB can issue a type-approval label which is affixed to the device to show that it has been evaluated in accordance with the HKCA standards. Although labeling is voluntary, manufacturers, suppliers and dealers are encouraged to use labels for consumer guidance.

## INDONESIA

Q2: Yes, there is regulation 102, 2000 on standardization. Currently drafting an act to include CA in addition to standardization that is expected to be issued in 2014.

Q3: It is both voluntary and mandatory. It includes government acceptance of ISO 90001 that is certified by a CAB that is accredited by an AB that has signed the MLA (voluntary). The Ministry of forestry issued regulation for sustainable management system that requires the CAB to be accredited by the Indonesia Accreditation Body (KAN) and using ISO/IEC 17021 and 17065 as references (mandatory).

Q4: Always. See details in answer to Q3. There are also regulations for wheat flour, 35/M-IND/PER/3/2011 and for bottled drinking water 69/M-IND/PER/7/2009.

Q5: Yes. The product sectors are food, electrical/electronic, timber.

Q6: The regulation states the use of international MRAs without stating the organization.

Q7: Through KAN, there are signed MLAs with IAF, PAC, APLAC, ILAC. Bilateral MRAs with SASO, BPS (The Philippines), CNAS (China), UKAS (UK), and JAS-ANZ (Australia-New Zealand).

Q8: In addition to the answer to Q7, there is active participation in the Association of South-East Asian Nations (ASEAN) which has an agreement on standards and CA harmonization covering such products as electrical/electronic, wood, cosmetics, automotive, rubber and medical devices.

Q9: There is a guidance document that explains the steps to implement the ID domestic standard as a technical regulation. The guidance refers to APEC GRP. The government recognizes ISO/IEC 17065, international/regional MLAs and MRAs and the competence of the CAB.

Q10: The ID guide on GRP (PSN # 301/2011) issued by the domestic standardization agency is mandated by law and establishes rules on standardization and CA.

Q11: The domestic standard on electrical installations (PUIL) is mandatory. The technical regulation is 008/2007. There are currently no regulations for medical-pacemakers that are notified to WTO.

Q12: The regulation covers both domestic and foreign suppliers.

Q13: According to the guide, the CA may include SDoC, 3rd party or a combination of the two.

Q14: Certification marks are required for such products as wheat flour, bottled drinking water, fertilizer, cement, cocoa bean, electrical/electronic.

## JAPAN

Q2: There is no law, regulations, rules or formal guidance specifying a CA general policy.

Q3: It depends on the sector. Laws against hazards and disturbances require 3rd party certificates. There are common rules to utilize CA in law.

Q4: Technical regulations occasionally include specific CA requirements.

Q5: Yes, Consumer Product Safety Act, Electrical Appliances and Material Safety Act, The Building Standards Act, The Fire Service Act, etc.

Q6: Yes, the Industrial Standardization Act, etc. cite ISO/IEC 17025.

Q7: The EU, Singapore, Philippines, Chinese Taipei, Thailand and the United States.

Q8: N/A.

Q9: N/A.

Q10: N/A.

Q11: The APEC LISF RHSC coordinates all medical device regulations. Contact [www.apec-rhsc.org/index.do](http://www.apec-rhsc.org/index.do) before conducting the survey. Solar PV system is required by Electricity Business Act. In case of integrated PV in buildings, it must satisfy the Building Standards Act.

Q12: N/A.

Q13: N/A.

Q14: There are no domestic certification marks in Japan.

## REPUBLIC OF KOREA

Q2: The Framework Act of National Standards describes the policy. Articles 21 (establishment of CA system), 23 (accreditation), and 25 (mutual recognition). See <http://elaw.klri.re.kr>

Q3: CA is being operated based on ISO/IEC 17011, 17025, etc. The Korean Laboratory Accreditation Scheme (KOLAS) manages all accreditation work of each ministry and department. For areas such as environment, safety and health, related ministries develop their own CA systems and apply to individual laws that describe the technical regulations.

Q4: Usually. The government operates around 103 laws related to technical regulations through 19 governmental organizations (ministries, agencies and

councils). The subordinate laws (e.g. notification) of these laws specify CA requirements.

Q5: Ordinances of the measurers act, high pressure gas safety control act, industrial standardization act, oil and oil alternative fuel business act, energy use rationalization act, electrical appliances safety control act, quality management and industrial products safety control act.

Q6: There are 39 laws complying with international standards (e.g. ISO/IEC17025) and MRAs such as ILAC/MRA and IAF/MLA including laws listed in Q5 above. IECEE CB test certificates and test reports are recognized that are issued by IECEE designated NCBs, since Korea is a member of the IECEE. CB Scheme.

Q7: The legal basis of MR of CA results with foreign bodies can be found in Article 3 (safety certification) of the Electrical Appliances Safety Control Act, Article 14 (safety certification) of Quality Control and Safety Management of Industrial Product Act. One of the best examples of MR of CA results with foreign economies is the APEC-TEL MRA for safety certification for electrical appliances. It enables the Korean market to accept CA results of foreign economies such as US, Canada, Singapore, Viet Nam and Chile.

Q8: Efforts are being focused for multilateral and bilateral cooperation with international/regional organizations through various programs. For example, active participation in ISO, IEC, ITU, ILAC, IAF, APLAC, and PAC as P-member.

Development and operation of own cooperation program to support the development of metrology and CA system to develop/revise domestic standards and to promote standards education of partner economies and regional organizations such as Viet Nam, Mongolia, Indonesia Myanmar, India, Bhutan, Nigeria, Kenya, South Africa, Peru, Bolivia, Brazil, Ecuador, Saudi Arabia, UAE, Oman, Uzbekistan, Kazakhstan and ARSO, GSO, COPANT, ACCSQ, PASC.

Q9: As an effort to implement GRP, comments are solicited from various stakeholders before newly developed and revised CA requirements are announced.

Q10: They are based on both, voluntary and government regulations. It depends on the related ministries' needs.

Q11: Electrical installation rules are enacted by the Electrical Appliances Safety Control Act, which includes CA requirements. Photovoltaic is so far voluntary but CA requirements for



medical devices are legislated by the Korea Food and Drug Administration (KFDA). For more information contact +82-2-509-7242, or [psd0@korea.kr](mailto:psd0@korea.kr); for medical, +82-43-719-3702. For information on legislation in English <http://elaw.klri.re.kr>.

Q12: Suppliers of other economies can have access to CA processes as domestic suppliers. For further information see website provided in Q11.

Q13: For medical devices only certification by a 3rd party is recognized.

Q14: It is mandatory to obtain KC (Korean certification) Mark for electrical appliances described in the related Act. This does not apply to medical devices but the product approval and registration by KFDA must be obtained before sale.

## MALAYSIA

Q2: Yes. 1. Under Standards of Malaysia Act 1996 (act 549). STANDARDS MALAYSIA has been appointed as the domestic accreditation body whose function among others is to accredit, in accordance with criteria and procedures approved by the Council, organizations that are engaged in CA and maintain a register of accredited organizations and of their marks of conformity. Also to establish and register under the Trade Marks Act 1976 the Department of Standards Malaysia's own accreditation symbols. 2) Cabinet's decision (2004). The three recommendations agreed upon are:

- a) Regulatory bodies to make it compulsory the usage of accredited test reports and certification under the current accreditation system of STANDARDS MALAYSIA or any other accreditation system recognized by STANDARDS MALAYSIA;
- b) STANDARDS MALAYSIA to be recognized as the domestic accreditation body for all CA activities. In relation to this, all testing and calibration laboratories and certification bodies operating in Malaysia are required to obtain accreditation from STANDARDS MALAYSIA; and
- c) The government is to give support to the laboratories and certification bodies accredited under the domestic accreditation system or other accreditation systems recognized by STANDARDS MALAYSIA.

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mariam@standardsmalaysia.gov.Tel: +603 8319 1445;

Q3: There are a few mechanisms where conformity assessment is practiced: 1) Through compliance to technical regulations which requires testing, certification and inspection to be performed accordingly as proof of compliance. This is mandatory in nature. 2) Though voluntary application by conformity assessment bodies through STANDARDS MALAYSIA for accreditation and other certification bodies and inspection bodies for certification and inspection purposes respectively.

Q4: Occasionally. A survey conducted in 2012 on identification of new requirement of mandatory standards in technical regulation conducted by STANDARDS MALAYSIA, revealed the need for explicit conformity assessment requirements as proof of compliance to technical regulations. Mechanisms identified are testing, certification, inspection and self-regulation.

Q5: Yes, we have identified the prescribed conformity rules in the technical regulations for regulated products.

Q6: ISO/IEC 17065, PAC MLA Quality Management System (QMS) - 5 November 1998; Environmental Management System (EMS) - 31 December 2005; Product Certification (PC) - 16 June 2009; IAF MLA Quality Management System (QMS) - 29 September 1999; Environmental Management System (EMS) - 9 February 2006 Product Certification (PC) - 9 July 2009; ISO/IEC 17025 & ISO/IEC 17020 APLAC MRA Testing - 14 November 2002; Calibration, 13 November 2003; Medical Testing - 18 April 2007; ILAC MRA Testing - 16 January 2003; Calibration - 19 November 2003; Malaysia is a member IECEX and IECEE CB Scheme. STANDARDS MALAYSIA is also the secretariat of the National Management Committee for IECEX and IECEE CB Schemes

Q7: Bilateral and multilateral FTAs; ASEAN MRAs.

Q8: All cooperation and joint work are in the framework of FTAs, ASEAN MRA, activities under APEC SCSC and standards bodies such as ISO and IEC.

Q9: Malaysia has appointed Malaysia Productivity Corporation (MPC) to spearhead GRP initiative in Malaysia. This initiative is also under the purview of National Development Planning Committee for of which among other responsibilities is to review and approve the development of technical regulations.

Q10: These are usually mandated by law.

Q11: Photovoltaic products are not regulated in Malaysia; medical devices are regulated under Medical Devices Act 2012 (Act 737).

Q12: Suppliers of similar products in other economies have access to conformity assessment process in the same manner as domestic suppliers.

Q13: Supplier's Declaration of Conformity (SDoC) is accepted for medical devices.

Q14: There is no certification mark for medical devices.

## MEXICO

Q 2: Mexico has policies and procedures for conformity assessment. It is called “Políticas y procedimientos para la evaluación de la conformidad. Procedimientos de certificación y verificación de productos sujetos al cumplimiento de normas oficiales mexicanas, competencia de la Secretaría de Economía” y sus modificaciones, known as “POLEVAS”. The document can be found at the following link:

[http://www.economia.gob.mx/files/comunidad\\_negocios/normalizacion/Mod\\_pol\\_pub\\_24101997.pdf](http://www.economia.gob.mx/files/comunidad_negocios/normalizacion/Mod_pol_pub_24101997.pdf)

Q3: The conformity assessment is used to determine the degree of compliance with the technical regulations (NOM) or compliance with voluntary standards (NMX), international standards or other specifications, requirements or features. This includes, inter alia, procedures for sampling, testing, calibration, certification and verification.

Q4: Always - Look at the Annexes 2 and 3 from POLEVAS.

Q5: Yes - POLEVAS Annex 2 and 3 for safety requirements on electric, electronics and household appliances, conformity assessment of safety and health at work, NOM-141-SSA1-1995 and NOM-001-SEDE-2005.

Q 6: The third party conformity assessment is preferred through the POLEVAS, regarding the accreditation basis established on the ISO/IEC 17011 general requirements for accreditation bodies accrediting conformity assessment bodies and ISO 9001 certification bodies. The accreditation entity in Mexico has signed agreements with IAF, ILAC, PAC, IAAC and APLAC.

Q7: The Mexican government only has one MRA related to telecommunications equipment testing (it is called “Acuerdo de Reconocimiento Mutuo en materia de pruebas de equipo de telecomunicaciones”) between the United States and Canada, laboratory recognition tire with the United States, testing laboratories in product safety with Canada and the United States, conformity assessment of telecommunications equipment with Canada and the United States and APEC-Toys MRA. There are others agreements signed between the Accreditation bodies that can be found at the following link:

<http://www.economia.gob.mx/comunidad-negocios/competitividad-ormatividad/normalizacion/nacional/evaluacion-de-conformidad/acuerdos-de-reconocimiento-mutuo>

Q8: Regarding Conformity Assessment, Mexico participates in ISO/CASCO, Technical Committee 112 of COPANT and IEC/CAB.

Q9: The Mexican government has developed new procedures based on international guides and standards available.

Q10: The requirements are mandatory for technical regulations. Voluntary standards may or may not follow them.

Q11: For Electrical installations:

- <http://200.77.231.100/work/normas/noms/2000/001sede.pdf>

For medical devices and pharmaceutical products:

- <http://www.cofepris.gob.mx/AS/Paginas/Registros%20Sanitarios/RegistroSanitarioDispositivosMedicos.aspx>
- <http://www.cofepris.gob.mx/MJ/Paginas/Acuerdos/AcuerdosSecretario.aspx>

Q12: The procedures are applicable for domestic/foreigners manufactures and importers.

Q13: The Supplier's Declaration of Conformity is not considered for the products of interest.

For medical devices and pharmaceuticals the "certification" reduces time of the marketing approval for allowing them to access the Mexican market.

Q 14: The products must have Mexican authorization to be sold in the domestic market. The certification mark is not mandatory for electrical products. For medical devices and pharmaceuticals it is required to present the marketing authorization approval from the domestic health authority.

## NEW ZEALAND

Q2: Use of CA by regulators is voluntary. Regulators specify the use in different ways, sometimes they make it mandatory (by either act of parliament or regulation) but there is no general policy on CA.

Q3: Regulators generally prefer to use 3rd party CA as it is generally cheaper than undertaking it on their own (at taxpayers' expense). The use of widely recognized CA also reduces unnecessary duplication of testing and inspection. It is up to the regulators on which approach they choose.

Q4: Usually. Pressure equipment, cranes and passenger ropeway regulations. Building. Building Consent Authority accreditation. Ministry for Primary Industry requirements, (tertiary level) for food testing. Electrical product safety and EMC regulations for industrial, scientific or medical equipment.

Q5: See details in answer to Q4.

Q6: Testing must be done in labs accredited to ISO/IEC 17025 and inspection by inspection bodies accredited to ISO/IEC 17020. In some instances there is a requirement for the accreditation to be done by the accreditation authority (IANZ) or an IANZ (APLAC/ILAC) MRA partner.

Q7: NZ/EU MRA on CA. CHIN/NZ FTA on electrical/electronic equipment. NZ is also a signatory to the APEC EE MRA.

Q8: IANZ is an active participant in APLAC and ILAC. Also work closely with NZ government in the negotiation of FTAs. IANZ receives no government funding so the work with other economies tends to be in the areas that benefit IANZ. In the past, NZ has also assisted other economies with training on specific accreditation, testing and inspection standards in China, Hong Kong China, Singapore and Chinese Taipei. Over the years, there has been active and close cooperative work with Australia.

Q9: Regulatory impact statements are required for all new regulations and these are examined to ensure that GRP principles are followed.

Q10: Yes. See answers to earlier questions.

Q11: There are no mandatory certification requirements for any products. For some high risk products (electrical declared article list) testing must be carried out in an accredited laboratory. However SDoC is still acceptable for market access. The same is for EMC testing for ISM equipment. There are no mandatory requirements for medical devices. Electrical installation must be carried out by a registered (approved) person. This is for registration, not for personnel certification.

Q12: Importers must meet the identical requirements as NZ suppliers.

Q13: SDoC is understood to be the main requirement.

Q14: There is no certification mark required.

## PAPUA NEW GUINEA

Q2: Yes. Section 5 (1e), 5 (1f) and 5 (1j) of the National Institute of Standards & Industrial Technology (NISIT) Act of 1993.

Q3: The NISIT Act of 1993 stipulates the Institute to be the standards & quality (conformance) authority in the economy. The Institute operates couple of conformity assessment schemes which are voluntary in nature. It is not mandatory for industries to comply with the Institute's conformity assessment programs. However, in some major government procurement and construction contracts, the contract bidders may be required to show proof of their ISO 9001, ISO 14001 and ISO 17025 certifications/ accreditations.

Q4: Occasionally. The 2 examples which can be shown here are: -

- Fish export regulation & standard; by the National Fisheries Authority. This standard also spells out clearly the kind of conformity assessment activities which shall be conducted on fish and fishery products for export.
- Food Sanitation Regulation; by Department of Health. This regulation clearly spells out the conformity assessment activities relating food and food safety.

Q5: For electrical products, the Regulatory Services Division of PNG Power will have to conduct verification tests on product samples and certify them before releasing into the market place. Similarly, for electronic/telecommunication items, this activity is implemented by Regulatory Services Division of the National Information and Communications Technology Authority. These authorities use the IEC and ITU-T standards/rules and their respective technical regulations to conduct the verification exercises.

Q6: Very rarely, although PNG is signatory to some of them.

Q7: PNG is signatory to the following mutual recognition arrangements: 1. APLAC and ILAC MRA's for laboratory testing 2. PAC MLA 3. APEC EE MRA for electrical and electronic goods (Part 1 only).

Q8: When they become available, our laboratories participate in the APEC/APLAC proficiency testing programs. Also, PNG does participate in the APEC Pathfinder Initiatives on Food Safety.

Q9: We are not yet too sure of this, but as the NISIT Act of 1993 is scheduled to be reviewed soon, this topic will surely be discussed as part of the review process.

Q10: Cannot really answer this one.

Q11: For electrical installation rules, please contact Mr. Watson Naso of PNG Power on telephone + 675 3243364 or email [wnaso@pngpower.com.pg](mailto:wnaso@pngpower.com.pg) For photovoltaics, please contact Mr. Alan Lari of Department of Petroleum & Energy on telephone + 675 3253233 or mobile # + 675 6973195. For medical equipment pace-makers, please contact Mr. Ambrose Kwaramb on telephone + 675 3251066 or email [akwaramb@datec.net.pg](mailto:akwaramb@datec.net.pg)

Q12: Get more information from the contacts listed in # 11 above.

Q13: It is not mandatory, but in some cases, importers of these products seek the views of the Institute on certificates provided by the manufacturers of these products. Most importers provide these documents directly to Customs and Quarantine at the ports of entry.

Q14: Not mandatory at this stage.



## PERU

Q2: Not exactly. There is only a reference in the following law: “Law of National Systems of Standardization and Accreditation (Legislative Decree 1033)”. This legal document establishes in its Article 25th that: “Periodically, the NAB will call to public entities that use the services of CABs in order to coordinate and design with them programs that promote body accreditation in specific areas of public interest.” Check the following link (in Spanish, there is no English version)

<http://www.villanuevaharo.com/publicaciones/DL1030%20SIST.%20NAC.%20NORMALIZACION%20Y%20ACREDITACION%20INDECOPI.pdf>

Q3: The government entities Ministries to authorize conformity assessment bodies (CAB) to control and monitoring of technical regulations. The requirement is that such OECs must be accredited in the economy or abroad. In other cases, government entities directly control and monitor using their own laboratories, even when they are not accredited.

Q4: Occasionally. The Sanitary Register of packaged foods (Ministry of Health) requires the involvement of accredited testing laboratories. The technical regulations about tires and electrical conductors (Ministry of Industry) require the intervention of certification bodies (by batch or mark of conformity). The certification of hydro-biological products safety for export requires the participation of accredited testing laboratories.

Q5: Yes, for packaged foods; tires; cables and conductors; batteries; pisco (Peruvian beverage); hydro-biological products; natural gas; liquid hydrocarbons; agricultural food safety

Q6: Hydro-biological products: ISO/IEC 17025; natural gas: IAF/MLA, ILAC/ MRA; agricultural food safety: ISO/IEC 17025 and ISO/IEC 17020.

Q7: Bilateral and multilateral FTAs; ASEAN MRAs.

Q8: Peru is receiving technical assistance and cooperation from Korea to implement a monitoring and control system in electrical and electronic products (certification of products).

Q9: The GRP is being developed at the level of the economies of the Andean Community (Bolivia, Colombia, Ecuador and Peru); expect implementation in those economies shortly. Those GRPs are based on the work of APEC.

Q10: Indeed, the implementation of the GRP has as one of its objectives that the control and monitoring of TR by government authorities (mandatory sector) is performed using accredited CABs (voluntary sector).

Q11: No.

Q12: Yes, the requirements are the same (no discrimination).

Q13: When the government buys these products, it may require both: SDoC or 3rd party. This is stated in the rules for bidding on products.

Q14: There no certification marks.

## THE PHILIPPINES

Q2: There is no general policy, but there are specific laws for different regulatory agencies.

Q3: Several approaches are being used such as those covered in ISO/IEC 17065, 17025, 17011; recognition of certificates from foreign regulatory as well as accredited CA bodies (imported telecommunication equipment); certification of farm practices based on domestic standards (PNS) (system certification); accreditation of organic certifying bodies (mandatory); testing for meat products; inspections, registration and issuance of certificates for health products.

Q4: Always. Farm practices to domestic standards and product compliance (that are based on international standards); recognition of laboratories that are accredited by the Philippine Accreditation Office (PAO) and others that are signatory to APLAC/ILAC MRAs; recognition of certificates from foreign regulatory or accredited CA bodies (imported telecom equipment); petroleum products quality based on PNS and check list of requirements for each type of application for cosmetics, health and processed food products.

Q5: Electrical /electronic consumer products and others (see link [www.bps.dti.gov.ph/component/content/article/122-list-of-products-under-mandatory-certification-as-of-22-august-2011.html](http://www.bps.dti.gov.ph/component/content/article/122-list-of-products-under-mandatory-certification-as-of-22-august-2011.html)), radio and telecommunications terminal equipment, organic, meat, fish products; animal feed, seeds, fertilizers and pesticides; sugar, rice, coconut, petroleum products, processed food and health products.

Q6: Yes, they cite those international CA standards and also Codex Alimentarius, OIE, International Plant Protection Convention (IPPC), ASEAN, or MR arrangements such as PAC, IAF/MLA, APLAC and ILAC/MRA.

Q7: ASEAN EEE MRA for electrical/electronic and telecom equipment (no formal MRA yet, but there is cooperation or joint work with other ASEAN economies for the implementation of the ASEAN Telecommunication Regulators Council (ATRC) Sectoral MRA for telecom equipment.

Q8: ASEAN and APEC CA initiatives such as Asian Harmonization Working Party for medical devices (AHWP); ASEAN Consultative Committee on Standards and Quality Medical Device Product WG (MDPWG); ASEAN Telecommunication Regulators Council (ATRC); Sectoral MRA for telecom equipment.

Q9: Harmonization of PNS with international or regional standards agreed upon in the ASEAN that are cited in technical regulations. Consultations with relevant stakeholders and public availability of technical regulations.

Q10: Standards are voluntary but become mandatory when cited in regulations; e.g. The Republic Act 9711 on food and drugs (BFAD) by establishing testing laboratories, upgrading its equipment, giving authority to retain its income, renaming it the FDA, etc., provides this authority and coverage of regulation of products subject of this law to FDA.

Q11: CA requirements for medical devices is mandated by law. For pacemakers the requirement is product registration (see [www.doh.gov.ph](http://www.doh.gov.ph), under doing business, under licensing, then under BHDT-Medical Non-radiation Device Regulation Division); Electrical and building codes are being implemented by local government units.

Q12: For pacemakers all requirements are on the web. But in order to market the product a local distributor is needed.

Q13: For medical devices as a whole, declaration of conformity is recognized and ISO certification by a 3rd party is required.

Q14: No certification mark for pacemakers. However, a certificate of product registration should be secured first based on the requirements specified in Q11. A corresponding registration number will be issued to be placed on the label of the pacemaker before the product can be placed on the market for distribution and sale.

## RUSSIAN FEDERATION

Q2: FEDERAL LAW, No. 184-FZ of 27 December 2002 “On Technical Regulating” (with amendments dated 09.05.2005, 01.05.2007, 01.12.2007, 23.07.2008, 18.07.2009, 23.11.2009, 30.12.2009, 28.09.2010, 21.07.2011, 30.11.2011 and 06.12.2011).

The Russian Federation’s legal framework for technical regulations (TRs), standards and conformity assessment systems is governed by international agreements of the Eurasian Economic Community (EurAsEC – members: Russian Federation, Kazakhstan, Belarus, Kyrgyz Republic, and Tajikistan) and of the Customs Union (CU – members: Russian Federation, Kazakhstan, and Belarus).

- Agreement on the Basics of Technical Regulations Harmonization of the Eurasian Economic Community Members (EurAsEC Agreement) of 24 March 2005
- Agreement on Implementation of Coordinated Policy in the Field of Technical Regulation, Sanitary and Phytosanitary Measures (EurAsEC Agreement) of 25 January 2008
- Agreement on Uniform Principles and Rules of Technical Regulation in the Republic of Belarus, Republic of Kazakhstan and the Russian Federation (CU Agreement) of 18 November, 2010.
- Rules of the Development of the Technical Regulations, approved by EurAsEC Interstate Council Decision No. 1175 of 17 August 2008 (EurAsEC Interstate Council Decision No. 1175);
- Statement on development, adoption, amendment and cancellation of Technical regulations of the Customs Union (Decision of the Council of Eurasian Economic commission № 48, 20 July 2012 r.)

These Agreements and Decisions established the main instruments of the common policy applied in the Russian Federation in the following areas:

- Harmonization of domestic legislation in the area of technical regulation
- Development and adoption of TRs of the CU and of EurAsEC stipulating mandatory and binding requirements for the goods subject to technical regulation
- Implementation of common procedure on development of technical regulations in the territory of each CU and EurAsEC Party
- Harmonization of standards and the implementation of relevant international standards as a basis for the elaboration of TRs
- Implementation of common forms and rules for conformity assessment
- Conducting conformity assessment (confirmation) of products or product-related production processes, installation, setup, operation (use), storage, carrying (transportation), sale and disposal, including testing and certification, as well as
- Accreditation and/or designation of certification (conformity confirmation) bodies and accreditation of test laboratories (centers) participating in the process of mandatory confirmation of conformity.

Q3: FEDERAL LAW, No. 184-FZ “On Technical Regulating” Chapter 1 General Provisions Article 3. Principles of technical regulating shall be carried out according to the following principles:

- application of uniform rules of an establishment of the requirements for products or related requirements for their designing (including research), manufacturing, construction, installation, adjustment, operation, storage, transportation, sale and recycling processes, for performance of works or rendering of services;
- conformity of technical regulating to a level of the economy's development, development of material base, and also to a technological level;
- independence of accreditation and certification bodies from manufacturers, sellers, executors and purchasers, including consumers;
- uniform system and rules of accreditation ;
- unity of rules and methods of researches (tests) and measurements when carrying out an obligatory conformity assessment;
- unity of application of the requirements of technical regulations irrespective of kinds or features of transactions;
- inadmissibility of restriction of a competition during accreditation and certification;
- inadmissibility of combination by one body of credentials for the state control (supervision), except for the control over activity of the accredited persons, with credentials for accreditation or certification;
- inadmissibility of combination by one body of credentials for accreditation and certification;
- inadmissibility of off-budget financing of the state control (supervision) over observance of the requirements of technical regulations;
- inadmissibility of simultaneous placing of the same credentials on two and more bodies of the state control (supervision) over observance of the requirements of technical regulations.

Chapter 4. Conformity assurance Article 18. The purposes of conformity assurance shall be carried out for the following purposes:

- authentication of conformity of products, designing (including research), manufacturing, construction, installation, adjustment, operation, storage, transportation, sale and recycling processes, works, services or other objects to technical regulations, standards, codes and conditions of contracts;
- assistance to purchasers, including consumers, in a competent choice of products, works, services;
- increase of competitiveness of products, works, services in the Russian and international markets;
- creation of conditions for provision of free movement of goods in the territory of the Russian Federation, and also for realization of the international economic, scientific and technical cooperation and international trade.

Article 19. Principles of conformity assurance

1. Conformity assurance shall be carried out on the basis of the following principles:

- availability of the information on a procedure of conformity assurance for the interested parties;

- inadmissibility of application of obligatory conformity assurance to the objects in relation to which the requirements of technical regulations are not established;
- establishment of the list of forms and schemes of obligatory conformity assurance regarding certain kinds of products in appropriate technical regulation;
- reduction of the terms of realization of obligatory conformity assurance and expenses of an applicant;
- inadmissibility of compulsion to realization of voluntary conformity assurance, including the certain system of voluntary certification;
- protection of property interests of applicants and observance of trade secrets regarding the data obtained during realization of conformity assurance;
- inadmissibility of substitution of obligatory conformity assurance with voluntary certification.

2. Conformity assurance shall be developed and applied similarly and *pari passu* irrespective of the economy and (or) place of an origin of products, realization of processes of designing (including researches), manufacturing, construction, installation, adjustment, operation, storage, transportation, sale and recycling, performance of works and rendering of services, kinds or features of transactions and (or) persons who are the manufacturers, executors, sellers, purchasers.

#### Article 20. Forms of conformity assurance

1. Conformity assurance in the territory of the Russian Federation may possess voluntary or obligatory character.
2. Voluntary conformity assurance shall be carried out in the form of voluntary certification.
3. Obligatory conformity assurance shall be carried out in the following forms: adoption of the supplier's declaration of conformity (hereinafter referred to as declaring of conformity); obligatory certification.
4. The order of application of the forms of obligatory conformity assurance is established by this Federal law.

Q4: Always.

FEDERAL LAW, No. 184-FZ "On Technical Regulating" Chapter 2 Technical Regulations, Article 7. Contents and application of technical regulations according to it. 3: The technical regulations shall contain the list and (or) description of objects of technical regulating, the requirements for these objects and the rules of their identification for the purpose of application of technical regulations.

The technical regulations shall contain the rules and forms of conformity assessment (including the schemes of conformity assurance, the order of prolongation of validity period of the issued certificate of conformity), defined taking into account the risk degree, the deadlines of conformity assessment regarding each object of technical regulating and (or) the requirements for terminology, packing, marking or labeling and the rules of their putting. The technical regulations shall contain the requirements of power efficiency and resource saving.

The conformity assessment shall be carried out in the form of state control (supervision), testing, registration, conformity assurance, adoption and commissioning of the object whose construction is finished, and in other forms. Obligatory requirements of technical regulations for products or for products and related requirements for their designing (including research), manufacturing, construction, installation, adjustment, operation, storage, transportation, sale and recycling processes, for the rules and forms of their conformity assessment, the rules of identification, the requirements for terminology, packing, marking or labeling and the rules of their putting have the direct action in the whole territory of the Russian Federation and may be changed only by inserting of amendments and addenda into corresponding technical regulation. All other similar requirements, not included in technical regulations, may not be obligatory.

Q5: THE FEDERAL LAW, No. 184-FZ “On Technical Regulating” Chapter 2 Technical Regulations Article 7. Contents and application of technical regulations.

Q6: THE FEDERAL LAW, No. 184-FZ, dated 27.12.2002 “On Technical Regulating” Chapter 5. Accreditation of certification bodies and test laboratories (centers) Article 31. Accreditation of certification bodies and test laboratories (centers)

1. Accreditation of certification bodies and test laboratories (centers) shall be carried out for the following purpose:

- assurance of the competence of certification bodies and test laboratories (centers) performing works on conformity assurance
- provision of trust of the manufacturers, sellers and purchasers, including consumers, to activity of certification bodies and accredited test laboratories (centers)
- creation of conditions for recognition of the results of activity of certification bodies and accredited test laboratories (centers).

2. Accreditation of certification bodies and test laboratories (centers) performing works on conformity assurance shall be carried out on the basis of the following principles:

- Voluntariness
- openness and availability of the information on procedures, rules and results of accreditation realization
- competence and independence of the bodies carrying out the accreditation
- inadmissibility of a competition restriction and creation of obstacles to usage of the services of certification bodies and accredited test laboratories (centers)
- provision of equal conditions to the persons applying for reception of accreditation
- inadmissibility of combination of powers for accreditation and conformity assurance
- inadmissibility of an establishment of limits for the accreditation documents validity in separate territories
- inadmissibility of combination of powers for accreditation with powers for the state control (supervision) over observance of the requirements of technical regulations, except for the control over activity of the accredited persons
- provision of confidentiality of the information obtained during realization of accreditation

- inadmissibility of granting of the paid consulting services to accreditation bodies.

2.1. Accreditation of certification bodies and test laboratories (centers) shall be carried out by the accreditation body of the Russian Federation (hereinafter referred to as the accreditation body).

3. The order of accreditation of certification bodies and test laboratories (centers) performing conformity assurance, including the order and conditions of issuing, renewal and assurance of accreditation certificates, suspension and termination of their validity, the order of certification of the experts for accreditation, the order of involvement and selection of experts for accreditation and technical experts for performance of works in the field of accreditation shall be established by The Russian Federation. Criteria of accreditation of certification bodies and test laboratories (centers) and the requirements for them shall be established by the federal executive body authorized by the Russian Federation, on the basis of the international standards.

4. The order of formation and keeping of the register of certification bodies and accredited test laboratories (centers), the register of experts for accreditation and presenting of data contained in them shall be established by The Russian Federation. Article 31.1. accreditation body.

1. Accreditation body shall:

- carry out accreditation of certification bodies and test laboratories (centers)
- issue, reissue and assure accreditation certificates, suspend or terminate the issued accreditation certificates;
- check of observance of the requirements established for certification bodies and accredited test laboratories (centers)
- keep the register of certification bodies, accredited test laboratories (centers) and experts for accreditation
- participate in preparation of programs for the educational institutions carrying out vocational training of experts in the field of accreditation
- participate in the international organizations for accreditation
- cooperate with accreditation bodies of the foreign states
- provide granting to applicants of the information on the order and rules of realization of accreditation
- establish a grievance procedure (claims) for action (inaction) of certification bodies and accredited test laboratories (centers)
- realize other functions defined according to the legislation of the Russian Federation.

2. The accreditation body shall bear responsibility for the made decisions, including the decisions for issue and reissue of accreditation certificates, for their assurance, and for suspension and termination of their validity. The accreditation body shall:

- provide objectivity and impartiality during accreditation of certification bodies and test laboratories (centers) and shall not take upon oneself an obligation from which inevitability of accreditation would follow expressly or by implication



- provide equal conditions to applicants applying for reception of accreditation, without dependence from quantity of the earlier accredited certification bodies and earlier accredited test laboratories (centers)
- provide confidentiality of the information obtained from certification body or test laboratory (center) in the course of realization of their accreditation, except for the cases when disclosing of such information is required according to the legislation of the Russian Federation;
- perform accreditation only on the basis of application for accreditation, containing in full volume the data on certification body or test laboratory (center) and on supposed scope of accreditation
- provide an easy access to the information on the accredited certification bodies and accredited test laboratories (centers)
- inform certification bodies and accredited test laboratories (centers) on change of criteria or accreditation rules.

The accreditation body shall abstain from any actions which can give rise to doubts in its impartiality, and also from consultations of certification bodies and test laboratories (centers) to be accredited.

3. The functions of the accreditation body are carried out by the authorized federal executive body. Notes With respect to accreditation, the representative of the Russian Federation explained that the main principles of the organization of the current system of accreditation were set out in Article 31 of Law No. 184-FZ and would continue to be implemented until the establishment of a single accreditation body in early 2012. Foreign applicants seeking accreditation in the Russian Federation's system of certification were required to apply to the respective accreditation body.

A uniform accreditation procedure was applied to both Russian and foreign certification bodies and laboratories; thus, the rules of accreditation were the same for all applicants. Further, certification bodies and test laboratories were accredited in accordance with ISO/IEC Guideline 58, Guideline 61, Guideline 65 and ISO/IEC Standard 17000, Standard 17011, and Standard 17025.

All of the accreditation procedures in Russia are based on standard ISO 17011. Thus, simplifying accreditation procedures and avoiding re-accreditation could be accomplished, inter alia, through the Agreements on mutual recognition of accreditation bodies, if the relevant accreditation body is a signatory of the ILAC or IAF MLA, or the relevant conformity assessment body participates for example, in an IEC scheme. Russia intended to become a member of ILAC after the establishment of its single accreditation body in early 2012. When accrediting a foreign conformity assessment body, a Russian accreditation body takes into account the equivalence of criteria and requirements to be addressed within the accreditation procedure in the economy where that conformity assessment body had been accredited, and such equivalence could simplify the accreditation procedure for the Russian Federation. However that accreditation of a foreign conformity assessment body or test laboratory by a foreign accreditation body fulfilling the requirements of ISO 17011 was not a necessary precondition by which foreign certification bodies and test laboratories could be accredited by a

Russian accreditation body and have their certificates and the results of their conformity assessment procedures accepted in the Russian Federation.

Q7: Recognition of conformity assessment certificates issued in foreign economies was carried out in line with interstate agreements and international certification systems to which the Russian Federation had acceded and, in such cases, did not require the conclusion of a mutual recognition or other Agreement. Those interstate agreements and international certification systems to which the Russian Federation had acceded and for which the Russian Federation recognized the results of conformity assessment procedures are as follows :

- Geneva Agreement concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts
- Brussels Convention on Reciprocal Recognition of Proof Marks of Handguns and Cartridges
- IEC Quality Assessment System for Electronic Components (IECQ)
- IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE)
- IEC Scheme for Certification to Standards for Electrical Equipment for Explosive Atmospheres (IECEX).

Q8: Cooperation in the Eurasian Economic Community (EurAsEC). Members are Russian Federation, Kazakhstan, Belarus, Kyrgyz Republic, and Tajikistan. Agreements and decisions are listed in it. Custom Union cooperation (Russian Federation, Kazakhstan, Belarus) Agreements and decisions are listed in it.

Q9: GRPs are support compliance with TBT obligations, in practice each of them could be strengthened to be more supportive of trade flows and includes three major parts or directions: • Establish internal procedures at several stages of the regulatory process can be better organized at relatively low cost to be more relevant to the specific functionalities of the TBT Agreement. The FEDERAL LAW, No. 184-FZ, dated 27.12.2002 “On Technical Regulating” Article 9. “Order of development, adoption, amendment and cancellation of technical regulations”, provides appropriate text (see below).

Provide regulatory impact assessment (RIA) is, in principle, directly relevant to the implementation of the TBT Agreement, but in practice RIA does not address many of the Agreement's specific obligations. In Russia each technical regulations are provided by RIA - friendly options that are suggested by TBT obligations.

Provide public consultations which are also directly relevant to the elements of the TBT Agreement, but in practice consultation does not effectively address many of the issues of the Agreement.

The FEDERAL LAW, No. 184-FZ, dated 27.12.2002 “On Technical Regulating” Article 9. “Order of development, adoption, amendment and cancellation of technical regulations,” provides appropriate text (see below). The Russian government set up mechanisms of internal coordination which seem well suited to promoting and safeguarding compliance with the requirements of the TBT Agreement. Notes 1 THE FEDERAL LAW, No. 184-FZ “On Technical Regulating” Article 9. Order of development, adoption, amendment and cancellation of technical regulations

1. The technical regulations may be adopted by the international treaty of the Russian Federation subject to ratification in an order established by the Russian Federation legislation, or according to the international treaty of the Russian Federation ratified in an order established by the legislation of the Russian Federation. Such technical regulations shall be developed, adopted and cancelled according to the international treaty of the Russian Federation ratified in an order established by the legislation of the Russian Federation. Before coming into force of the technical regulation adopted by the international treaty of the Russian Federation subject to ratification in an order established by the legislation of the Russian Federation, or according to the international treaty of the Russian Federation ratified in an order established by the legislation of the Russian Federation, the technical regulation may be adopted by the federal law or by the order of the President of the Russian Federation, or by decree of The Russian Federation, or by legal document of the federal executive body for technical regulating according to provisions of this Federal law. The technical regulation developed in an order established by this article shall be adopted by the federal law or by decree of The Russian Federation in an order established accordingly for adoption of federal laws and decrees of The Russian Federation according to provisions of this Federal law.

2. Any person may be the developer of the draft technical regulation.

3. The notice on development of the draft technical regulation shall be published in print of the federal executive body for technical regulating and in the information system of general use in the electron-digital form. The notice on development of the technical regulation shall contain the information for what products or related requirements for their designing (including research), manufacturing, construction, installation, adjustment, operation, storage, transportation, sale and recycling processes there will be established the developed requirements, with summary of the purposes of this technical regulation, substantiation of necessity of its development and specification of those developed requirements which differ from provisions of corresponding international standards or obligatory requirements being in force in the territory of the Russian Federation at the moment of development of the draft technical regulation, and the information on a way of acquaintance with the draft technical regulation, the title or surname, name and patronymic of the developer of the draft technical regulation, postal address and e-mail for receipt of written remarks from the interested parties.

4. From the moment of publication of the notice on development of the draft technical regulation, this draft technical regulation shall be accessible to interested parties for acquaintance. The developer is obliged, on request of the interested party, to provide a copy of the draft technical regulation. The payment for this copy may not exceed an expense for its manufacturing. The developer shall complete the draft technical regulation taking into account the remarks of interested parties received in writing, shall organize public discussion of the draft technical regulation and shall make the list of remarks of the interested parties received in writing with a summary of the content of these remarks and results of their discussion. The developer is obliged to keep the remarks of interested parties received in writing till the day of coming into force of the technical regulation, adopted by appropriate legal document, and present them to deputies of the State Duma, to representatives of the federal executive bodies and to expert commissions for technical regulating, specified in clause 9 of this article, at their requests. Time period of public discussion of the draft technical regulation since the date of publication of the notice on development of the draft technical regulation till the day of

publication of the notice on termination of the public discussion may not be less than two months.

5. The notice on termination of public discussion of the draft technical regulation shall be published in the print of the federal executive body for technical regulating and in the information system of general use in the electron-digital form. The notice on termination of public discussion of the draft technical regulation shall include the information on a way of acquaintance with the draft technical regulation and the list of remarks of the interested parties received in writing, and also the title or surname, name and patronymic of the developer of the draft technical regulation, postal address and e-mail for contact with the developer. From the date of publication of the notice on termination of public discussion of the draft technical regulation, the finalized draft technical regulation and the list of remarks of the interested parties received in writing shall be accessible to interested parties for acquaintance.

6. The federal executive body for technical regulating is obliged to publish in the print the notice on development of the draft technical regulation and termination of public discussion of this draft within ten days from the moment of payment for publication of notices. The order of publication of notices and the size of payment for their publication are established by The Russian Federation. Notes 2 :The EurAsEC Agreements on the Basics of TR Harmonization and on TR Policy Coordination; the CU Agreements on Uniform TR Principles, on Mandatory Conformity Assessment, and on Mutual Recognition of Accreditation Bodies; and Law No. 184-FZ provided for the implementation of the following principles based on the provisions of the TBT Agreement:

- Application of non-discrimination and a domestic treatment regime. TRs were to be applied in the same manner and to the same extent irrespective of the economy and/or place of origin of products, the nature and details of the transactions and/or natural or legal persons (Article 7(6) of Law No. 184-FZ).
- Elimination of technical barriers to trade. Requirements of TRs must not create any barriers to business activity beyond the levels necessary to achieve legitimate objectives, such as the protection of human life or health, property, environment, life or health of animals and plants, and prevention of actions that might mislead consumers (Article 5.1 of the EurAsEC Agreement on TR Policy Coordination); as well as for the purpose of ensuring energy efficiency and resource saving (Articles 6(1) and 7(2) of Law No. 184-FZ and Article 4.2 of the CU Agreement on Uniform TR Principles); and removing unnecessary restrictions in mutual trade (Article 2.1 of the Agreement on the Basics of TR Harmonization).
- Harmonization of TRs with relevant international analogues. (Articles 7(8) and 7(9) of Law No. 184-FZ, 5.2 of the EurAsEC Agreement on TR Policy Coordination and Articles 4.4 and 4.5 of the CU Agreement on Uniform TR Principles). Harmonization of conformity assessment procedures with relevant international analogues.
- Harmonization and voluntary application of standards. Standardization must be carried out according to the principle of use of a relevant international standard as the basis for development of a domestic standard, except where such documents do not comply with purposes of adoption of technical regulations, including due to the effects of climatic and geographic factors or technology problems. (Article 12 of Law No. 184-FZ and Article 8.1(d) of the EurAsEC Agreement on TR Policy Coordination).

***Transparency in the development of TRs and standards (Articles 9 and 9.1 of Law No. 184-FZ), CU Commission Decision 527, EurAsEC Interstate Council Decision 1175***): Any legal or natural person, foreign or domestic, or governmental or nongovernmental body may act as the developer of a draft TR. A notification about the development of a draft TR must be published in the print media of Rosstandart, on the official web-sites of the government body on technical regulation (MIT), the CU Commission or EurAsEC, as relevant at an early appropriate stage in its development.

The notification must contain information on name and object of the TR; object characteristics in relation to which the requirements had been developed, with a summary of the purpose of the TR. The notification would specify whether the requirements being developed differed from relevant international standards or obligatory requirements valid in the territory of the Russian Federation and would indicate the source of information on the draft TR (i.e., the name of the developer of the given draft TR, as well as his contact information for the receipt of written comments from interested persons and the last day of for the submission of comments).

The draft TR would be available to interested persons as of the date of publication of this notification. The developer was required to supply, upon demand, any interested person with a copy of the draft TR. The payment for providing the copy was not to exceed the cost of its issuance. The developer was required to carry out a public consultation on the draft TR, consolidate written comments received from interested persons, provide responses to comments received and update the draft TR taking into account the written comments received.

The developer was required to save the written comments received from interested persons up to the date of entry into force of the TR, and, upon request, to hand them over to\ representatives of the government bodies of the Parties on technical regulation (e.g., in Russia, MIT) and the CU Commission or the Interstate Council of EurAsEC as relevant

In all cases, expert examination of a draft TR was carried out by an expert committee on technical regulation, composed of, inter alia, representatives of relevant government bodies, research institutions, self-regulated organizations, public associations of entrepreneurs and consumers. Meetings of the expert committee were held in open session, and its conclusions and recommendations must be subject to mandatory publication in the print media of Rosstandart and in the public information system in electronic digital form. The procedure for the publication of such conclusions and the amount of charge for their publication was established by The Russian Federation. The period for public discussion of the draft TR - from the date of publication of the notification about development of the draft TR up to the date of publication of the notification about completion of the public discussion - could not be less than two months.

The notification about completion of public discussion on the draft TR had to be published in the print media of Rosstandart and on the official websites of the government body on technical regulation (MIT) and the CU Commission and EurAsEC, as relevant, in electronic form. The notification about completion of the public discussion would include the sources of information on the draft TR, the list of written comments received from interested persons, responses to comments received, and the name of the developer of the draft TR, along with his/her contact information.

From the date of publication of the notification about completion of the public discussion, the updated draft TR and the list of written comments received would be available to interested persons. (Article 9 of Law No. 184-FZ, CU Decision 527, EurAsEC Interstate Council Decision 1175).). Natural and legal persons also could propose draft TRs to MIT for the Ministry to decide whether development of the TR was reasonable. In case of a positive decision, MIT would submit a proposal to develop a TR to the CU Commission or EurAsEC, as appropriate. Procedures for development of a TR were set out in CU Commission Decision 527 or EurAsEC Interstate Council Decision 1175 respectively. .

Establishment of conformity assessment procedures (including the criteria by which the Russian Federation designated or otherwise recognized conformity assessment bodies and their results) was according to the following principles: non-discrimination between domestic and imported products and among suppliers of imported products, both in terms of procedures and in terms of fees; proportionality of procedures to the level of risk; transparency and predictability of the procedures; and protection of confidentiality.

Recognition of conformity assessment results in accordance with international treaties of the Russian Federation and other international arrangements: Documents of the confirmation of compliance, marks of compliance and reports of research (tests) and measurement of products, obtained outside the Russian Federation, could be recognized in accordance with the international treaties of the Russian Federation (Article 30 of Law No. 184-FZ and Article 5 of the CU Agreement on Mandatory Conformity Assessment) and other international arrangements. Russia intended to join to ILAC which will require mutual recognition of results of all ILAC laboratories and assessment bodies. For this purpose establishment of a single accreditation body was provided to be accomplished by the end of 2011. Before joining ILAC, Russia was ready to conclude bilateral and multilateral arrangements with interested economies, including recognition of results of activity of third-economy certification bodies.

TRs were to contain requirements in terms of performance of product characteristics or their related processes or production methods, including design criteria (including testing), production, construction, assembly (setup), operation, storage, transportation, realization and utilization, as well as rules of identification, forms, schemes and procedures of assessment (confirmation) of compliance, rules for identifying the requirements for terminology, packing, marking or labeling rules and their application and reclamation, rather than requirements regarding design or descriptive characteristics, except where the purposes of adopting such TRs could not be achieved in the absence of requirements in respect of design and descriptive characteristics in view of the risk of damage (Article 7(4) of Law No. 184-FZ; Article 2.2 of the EurAsEC Agreement on the Basics of TR Harmonization; and Article 4.3 of the CU Agreement on Uniform TR Principles)

Q10: Conformity assessment of products is carried out in the Russian Federation in accordance with the Federal Law "On Technical Regulating" Conformity assessment process in Customs Union is being carried out in accordance with the International Agreements signed by the member-states of the Customs Union.

Q11: Electrical equipment is covered by Technical regulations of the Customs Union: "On the security of low-voltage equipment" and "On the safety of machinery and equipment", which will come into force on 15 February 2013.



Depending on the type of electrical equipment it may be subject to mandatory certification or declaration of conformity. The procedure of mandatory conformity is specified in the relevant Technical regulations of the Customs Union. The above mentioned information is downloaded on the website of the Customs Union ([www.tsouz.ru](http://www.tsouz.ru)). After the procedure of conformity compliance to the Customs Union Technical regulations is completed, the products are marked with a single mark of conformity in the market of the member-states of the Customs Union. The Statement on the single mark of products in the market of the Customs Union was adopted on 15 July 2011, Decision № 711. Until 15 February 2013 electrical equipment were covered by domestic technical regulations "On safety of low-voltage" and "On the safety of machines and equipment."

The information on the Technical regulation requirements and procedure of conformity assessment is downloaded on the website of the Federal Agency for Technical Regulation and Metrology ([www.gost.ru](http://www.gost.ru)). The list of certification bodies is downloaded on the website of the Federal Service for Accreditation ([fsa.gov.ru](http://fsa.gov.ru)). Medical equipment is a subject to mandatory conformity assessment (according to the Decision of The Russian Federation of 1 December 2009 № 982 "On approval of the single list of products subject to mandatory certification, and a single list of products subject to the Declaration of Conformity."

In accordance with the abovementioned decision pacemakers are subject to the Supplier's Declaration of Conformity. The order of arrangement and registration of Declaration of Conformity is specified by statement of The Russian Federation of July 7, 1999 № 766. After the procedure of conformity assessment in the form Declaration the products are marked by mark GOST R 50460-92. Photovoltaics are not the subject to the mandatory conformity assessment according to the Decision of The Russian Federation of 1 December 2009 № 982 "On approval of the single list of products subject to mandatory certification, and a single list of products subject to the Declaration of Conformity."

Conformity assessment is voluntary and may be carried out within GOST R system certification.

Q12: According to the FEDERAL LAW, No. 184-FZ "On Technical Regulating" conformity assessment process in Russian Federation is carried out by a certification body accredited in compliance with established order. Both Russian or foreign legal entity, accredited in accordance with the requirements established in the Article 31 may be as a certification body.

Q13: According to the FEDERAL LAW, No. 184-FZ "On Technical Regulating," Article 30 Documents on the products conformity compliance, marks of conformity, reports of testing (tests) and measurement may be recognized in accordance with the International agreement of the Russian Federation.

Q14: THE FEDERAL LAW, No. 184-FZ "On Technical Regulating" Article 27. Mark of market access

1. Products, whose conformity to the requirements of technical regulations is assured is assured in an order provided by this Federal law, shall be marked with a mark of market access. The image of the mark of market access shall be established by The Russian Federation. The given mark is not the special protected mark and shall be put for the information purposes.

2. Marking with a mark of market access shall be carried out by an applicant independently by any convenient way. The features of products marking with a mark of market access shall be established by technical regulations. Products, whose conformity to the requirements of technical regulations is not assured in an order established by this Federal law, may not be marked with a mark of market access.



## SINGAPORE

Q2: Yes, there are three regulations as follows: 1) 'Consumer Protection (Safety Requirements) Regulations' for Controlled Goods (electrical and gas household appliances) 2) 'SPRING Singapore (Conformity Assessment) Regulations' for certification and testing of Controlled Goods 3) 'Consumer Protection (Consumer Goods Safety Requirements) Regulations 2011' for consumer goods.

Q3: Generally, there are no preferred conformity assessment approaches by the government as the Regulations allow SPRING to impose documents and information as deem fit.

Q4: Never.

Q5: Yes, we have three information booklets for Conformity Assessment Body and Suppliers as follows: 1) 'Consumer Protection (Safety Requirements) Registration Scheme Information Booklet' for Controlled Goods 2) 'Consumer Protection (Consumer Goods Safety Requirements) Regulations 2011 Information Booklet' for consumer goods 3) 'SPRING (Conformity Assessment) Information Booklet' for Conformity Assessment Body.

Q6: Yes we use ISO/IEC 17025, ISO/IEC 17065 and IECEE CB Scheme.

Q7: We have following MRAs on the sectoral annex on EEE: -ASEAN EE MRA -APEC EE MRA -ANZSCEP (between Singapore and New Zealand) -A-S MRA (between Singapore and Australia) -JSEPA (between Singapore and Japan.)

Q8: Not applicable under our scheme.

Q9: Use international standards where possible. Participate in international foras. Close collaboration with key stakeholders.

Q10: Based on voluntary agreements and not mandated by law.

Q11: Not applicable.

Q12: Not applicable.

Q13: Not applicable.

Q14: Not applicable.

## CHINESE TAIPEI

Q2: Yes. The “Commodity Inspection Act”

(<http://www.bsmi.gov.tw/wSite/ct?xItem=20603&ctNode=3563&mp=2>); include provisions about the general policy for conformity assessment. However, for products that are under the jurisdictions of other regulatory authorities, such as pharmaceuticals, medical devices, telecommunication equipment and motor vehicles, the conformity assessment policy are regulated by different laws.

Q3: Generally speaking, the approach of third-party certification or obtaining approval from the regulatory authorities is preferred in our government’s conformity assessment practices. A move towards expanding the scope of products covered by the SDoC approach is now under discussion.

Q4: Always. In the announcements made based on the Commodity Inspection Act, the conformity assessment requirements are explicitly stated. For example, the announcement for sunglasses to be subject to mandatory inspection specified Declaration of Conformity as the conformity assessment procedure; and that for power supplies specified Registration of Product Certification as the conformity assessment procedure. For automotive sector, the conformity assessment requirements are specified in all technical regulations of “Vehicle Safety Testing Directions.”

Q5: The conformity assessment procedures for specific products are specified in the respective technical regulations. Please see the examples provided in the answer to Q4.

Q6: (1) Article 4 of the Regulations Governing Recognition of Designated Testing Laboratory for Commodity Inspection requires that testing laboratories apply for recognition by the Bureau of Standards, Metrology and Inspection should conform to CNS 17025 or ISO/IEC 17025, and be accredited by the Taiwan Accreditation Foundation.

(2) Article 21 of the Regulations Governing Recognition of Designated Testing Laboratory for Commodity Inspection, the National Certification Body (NCB) and its associated CB Testing Laboratory (CBTL) under the IECEE CB Scheme allows CBTLs to apply to the BSMI for registration through their NCBs.

(3) For pharmaceutical products, the PIC/S GMP Guide and ISO/IEC 17025 are cited in the conformity assessment rules.

Q7: (1) Mutual Recognition Arrangements on acceptance of conformity assessment were concluded with Singapore, New Zealand and Japan for electrical and electronic products. (2) For telecommunication equipment, Chinese Taipei is taking part in Phase I with 5 APEC economies (Australia, Canada, Hong Kong China, Singapore and the United States) and Phase II with Canada.

Q8: For electrical and electronic products, Chinese Taipei participates in APEC EE MRA Phase I. For pharmaceuticals, Chinese Taipei participates in the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S).

Q9: Conformity assessment requirements are developed based on risk assessment and hazard analyses. For purpose of transparency, the proposals are made publicly available for commenting.

Q10: Not sure about the meaning of this question. If we understand it correctly, the IAF MLA is referenced as one of the alternatives for recognition of ISO 9001 certificates under the RPC scheme in our Article 2 of “Directions for Recognition of Quality Management Systems Certification Bodies.” A quality management system certification body (hereinafter referred to as CB) that applies for recognition (hereinafter referred to as applicant) shall meet one of the following requirements: 1) Being accredited by the Taiwan Accreditation Foundation, Chinese Taipei; or, (2) Being accredited by an accreditation body (hereinafter referred to as AB) that is located in the same economy as the applicant and is a member of the Multilateral Recognition Arrangements (MLA) of the International Accreditation Forum, Inc. (IAF) or the Pacific Accreditation Cooperation (PAC).

Q11: No photovoltaic products are required to be subject to mandatory inspection in Chinese Taipei. Regarding medical equipment-pacemakers, in according with the Pharmaceutical Affairs Act, manufacturers must apply for a GMP/QSD license, and the products must apply for registration license. In addition to domestic regulations, Chinese Taipei FDA also adopts international standards such as ISO 13485, ISO 14971, and product specific safety assessment standards such as ISO 14708-2 and ISO 14155 for pacemakers. For more information, please visit <http://www.fda.gov.tw/EN/law.aspx>;

Q12: The conformity assessment process of pacemakers is the same for domestic and foreign suppliers.

Q13: SDoC is not used for pacemakers. Registration License shall be obtained before marketing.

Q14: Regarding pacemakers, according to Pharmaceutical Affairs Act, products require product licenses before sale. Licenses should be issued by TFDA upon approval of conformity assessment.

## THAILAND

Q2: Yes, by using Common Submission Dossier Template which is for the licensing and notification of medical devices. For more details, contact Ms.Suhoung / Mr. Chaiyapan responsible for these two types of products. [suhoung@fda.moph.go.th](mailto:suhoung@fda.moph.go.th); [chaiyapan@fda.moph.go.th](mailto:chaiyapan@fda.moph.go.th)

Q3: Via the expertise outside the office, especially through academic institutions.

Q4: Usually. In the application form according to the Ministerial Regulation, for example, the product's name, scope, essential principle of safety and performance, device description, summary of design verification and validation, risk analysis.

Q5: Currently, only for the licensing and notification of medical devices, e.g. for condoms, HIV test kit, contact lenses, physical therapy products.

Q6: Only for condoms which have to comply with ISO 4074 and the lab test must be ISO 17025 accredited.

Q7: Maybe in the near future among ASEAN economies.

Q8: Within ASEAN economies via ACCSQ-MDPWG. This working group planned to meet twice a year to cooperate about the regulation.

Q9: Will try to initiate GRP within our organization for the new coming laws.

Q10: Yes, still based on voluntary agreements.

Q11: This task is operated by another organization, medical engineering division, Department of Health Services and Support.

Q12: N/A

Q13: N/A

Q14: N/A

## THE UNITED STATES

Q2: Yes. The National Technology and Advancement Act (NTTAA) and OMB Circular A-119 require NIST to coordinate Federal, State and local standards and conformity assessment activities with those of the private sector. The law also requires NIST to develop guidance to federal agencies on conformity assessment with the goal of eliminating unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures. The guidance was published in August 2000 and is available at <http://gsi>.

In addition, the American National Standards Institute, a private sector organization, has published the United States Conformity Assessment Principles, originally approved in May 2007 and republished in 2011. It is available at [www.ansi.org/uscap](http://www.ansi.org/uscap).

Q3: The U.S. government conformity assessment approach is based on the above-cited guidance and on the relevant principles of the WTO TBT Agreement.

The guidance provides, among others, that conformity assessment programs considered by agencies should have a sound rationale that agencies should seek public comments before launching programs that agencies should consider the results of conformity assessment carried out by other agencies and recommends the use of relevant international standards.

The WTO TBT requirements give additional clarity and focus to conformity assessment activities in the U.S. They include that conformity assessment activities do not create unnecessary obstacles to trade, that they be open and transparent and provide all applicants with equal treatment and that they be based, to the extent feasible, on appropriate international standards and procedures.

Q4: Occasionally. The Consumer Product Safety Improvement Act (CPSIA) calls for testing of children's products in laboratories accredited by an accreditation body that is a signatory to the ILAC Mutual Recognition Arrangement.

The U.S. electrical installation code (ANSI/NFPA 70) which is adopted as law in most States and local jurisdictions in the U.S., includes specific conformity assessment requirements for certain types of products and installations. Most of the provisions in this document are also included in the regulations of the US Occupational Health and Safety Administration (OSHA) which has federal jurisdiction for safety in the workplace.

The U.S. Coast Guard (USCG) regulates lifesaving and fire safety equipment and materials and requires that tests to show conformity with its requirements be carried out by independent laboratories accredited by an accreditation body that is a signatory to ILAC MRA.

Q5: Yes. Regulatory agencies, when implementing laws for specific products or family of products may develop conformity assessment programs. In addition to the examples cited in question 4, electrical products installed in hazardous locations, in healthcare facilities, in nuclear power plants, and others, have conformity assessment procedures to fulfill to demonstrate their safety.

Q6: Some of the rules cite international conformity assessment standards. In the examples cited in question 4, the laboratories have to meet ISO/IEC 17025 and the accreditation bodies have to meet ISO/IEC 17011.

ISO 9001 requirements are referenced in the FDA guidelines for Good Manufacturing Practice. EPA has a program to qualify labs for testing lead that is based on international guides and standards. FCC has procedures to minimize radiation interference from consumer products based on IEC/CISPR rules and standards. When the FCC requires that third party testing be done, it specifies that the laboratory must be accredited to ISO/IEC 17025 by an accreditation body that meets ISO/IEC 17011.

Q7:

1. U.S.-EU MRA Agreement on Mutual Recognition Between the European Community and the United States of America
2. U.S.-EEA EFTA States MRA Agreement on Mutual Recognition Between the United States of America and the EEA EFTA States
3. APEC Tel MRA Asia Pacific Economic Cooperation Mutual Recognition Arrangement for Conformity Assessment of Telecommunications Equipment
4. CITEL MRA Inter-American Telecommunication Commission Mutual Recognition Agreement for Conformity Assessment of Telecommunications Equipment
5. U.S.-Japan MRA US-Japan Mutual Recognition Agreement
6. US-Israel MRA
7. US-Mexico MRA Mutual Recognition Agreement between the Government of the United States of America and the Government of the United Mexican States for Conformity Assessment of Telecommunications Equipment Mutual Recognition Agreement between the Government of the United States of America and the United Mexican States for conformity assessment of telecommunications equipment

Q8: The U.S. government has formal regulatory dialogues with two APEC economies, Canada and Mexico. It also has cooperative agreements with Australia, Peru, Singapore and Chile and is in the process of negotiating with the Trans-Pacific Partnership including Brunei, Malaysia, New Zealand, Singapore and Viet Nam. It also undertakes numerous initiatives with other APEC economies to engage in dialogue and exchange of information.

Q9: When developing regulations, the U.S. government follows the Administrative Procedures Act (APA). The APA requires that proposed rules (including technical requirements and conformity assessment procedures) be submitted to public comment and that all comments received be addressed.

The Federal Register (daily publication akin to an Official Journal) publishes proposed rules and requests comments from the public, then publishes the responses to comments received and, if deemed necessary, may publish a new draft rule. Final rules are published in the Federal Register and codified in the Code of Federal Regulations (CFR).

Q10: No

Q11: For electrical installations, as explained above, a private sector standard, ANSI/NFPA 70 is adopted as law in most States and local jurisdictions in the U.S. and it includes both installation rules and specific conformity assessment requirements for certain types of products.

There are no mandatory regulations for photovoltaics in the U.S., so therefore there are no mandatory conformity assessment requirements.

For pacemakers, as well as most high risk medical devices, the US requires a pre-market approval (PMA) submittal to FDA that includes submission of clinical data. Manufacturers must establish and follow a quality system to help ensure that their products consistently meet applicable requirements and specifications. The quality systems for FDA-regulated products are known as current good manufacturing practices (CGMP's). CGMP's are consistent, to the extent practicable, with applicable international standards. Also FDA may audit manufacturing facilities for GMP compliance every two years.

Q12: Yes, they do. Suppliers of similar products from any economy have access to conformity assessment processes in the same manner as those in the U.S.

Q13: Suppliers Declaration of Conformity is widely accepted in the U.S. for a large variety of products.

For electrical installations and products, it depends. In ANSI/NFPA 70 there are rules for 3rd party and for SDoC. In general low voltage equipment used in the homes, workplace environment, commercial buildings and places where the public might come into contact with, is required to be 3rd party certified. Other equipment, such as one of a kind, high voltage utility is usually SDoC.

For photovoltaics, there are no mandatory regulations. However, on a voluntary basis, there are third party certification programs that are used by industry to demonstrate that products comply with voluntary standards.

For pacemakers, there is no mandatory third party certification in the U.S.

Q14: No, there are no mandatory marks. However, many products carry 3rd party certification marks that are very well accepted in the marketplace, notably for a wide range of electrical consumer products.

## VIET NAM

Q2: Yes, including the law on standards technical regulations ([www.tcvn.gov.vn](http://www.tcvn.gov.vn)). Also, the technical regulations on nuclear radiation safety.

Q3: There are the following 8 approaches: Type testing; type testing and assessment of the production process, surveillance by testing or inspection of samples taken from the market; type testing and assessment of the production process, surveillance by testing or inspection of samples taken from the factory combined with the assessment of the production process; type testing and assessment of the production process, surveillance by testing or inspection of samples taken from the factory and the market combined with the assessment of the production process; type testing and assessment of the production process, surveillance by testing or inspection of samples taken from the factory or the market combined with the assessment of the production process; assessment and surveillance of management system; testing, assessment of lots of goods and products; testing or calibration all goods and products.

Q4: Usually, including technical and management requirements;

Q5: Yes, including laws on standards and technical regulations, on quality of good and product, on food safety. Decree 132/2008/ND-CP - Providing in detail for implementation of a number of articles of the Law on quality of good and product;

Q6: Yes, including TCVN ISO/IEC 17025; TCVN ISO/IEC 17065 (CAB of product); TCVN ISO/IEC Guide 65, recognition of accreditation result of APLAC/ILAC/IAF.

Q7: Including ASEAN MRA on Dental Practitioners; ASEAN MRA on Medical Practitioners; ASEAN Sectoral MRA for Good Manufacturing Practice (GMR); ASEAN Electrical and Electronic Equipment MRA (ASEAN EE MRA); APEC Electrical and Electronic Equipment MRA (APEC EE MRA); ASEAN MRA of Product Registration Approvals for Cosmetics; ASEAN MRA on architectural services; ASEAN MRA on technical services.

Q8: Participating in the ASEAN ACCSQ Working Group on Standards and MRA (WG1) and ACCSQ Working Group on Accreditation and CA (WG2).

Q9: Including following steps of implementing GRP: I. Process of RIA: Determine the needs of technical regulations; determine objectives; determine the subjects (stakeholders) to be impacted; consulting with stakeholders; collect, analyze and process information; II. The process of RIS (The regulation impact statement: RIS for draft regulations; RIS for implemented regulations.

Q10: Yes, they are based on Law 17/2008/QH 12 (The promulgation of legal documents of the national assembly).

Q11: No.

Q12: There is no regulation for these products.

Q13: There is no regulation for these products.

Q14: Products that are considered hazardous and covered by regulations (QCVN), they are marked with CR mark before sale.



# Appendix B. Survey on Compliance with Article 5 of the WTO TBT Agreement

After the original survey, a follow-up questionnaire was circulated requesting details on specific actions taken to comply with Article 5 of the WTO TBT Agreement. This survey was conducted April 18-April 26, 2013. Responses were received from Australia, Canada, Hong Kong China, Mexico, New Zealand, Chinese Taipei, and Viet Nam. All indicated a “yes” response to all the questions noting that they comply with the WTO TBT obligations.

The economies were asked:

- Do you notify WTO members of all of proposed technical regulations that contain conformity assessment requirements, and proposed conformity assessment requirements that are issued separate from the technical regulation?
- Is a comment period provided enabling other Economies to submit comments on these proposed measures?
- Are the comments received from other Economies considered and taken into account?
- Do you follow the other provisions related to conformity assessment in Article 5 of the WTO TBT Agreement?
- Please describe any other actions you take to support Good Regulatory Practice.