



Self-Certification

Suppliers Declarations of Conformity

Conformity Assessment

- Determining that relevant requirements are fulfilled
 - Sampling
 - Testing
 - Inspection
 - **Suppliers Declaration of Conformity**
 - Certification
 - Registration
 - Accreditation

Background

- Historically the primary mechanism for establishing conformity to product requirements

Why was the standard developed?

- Need for national/international recognition of effective certification programs
 - Facilitate trade
 - Increase international acceptance of products

Typical Use

- Low risk associated with non-conformity
- Market/regulations capable of addressing non-conformities

Chronology

- 1970's – ANSI program for accrediting certification programs
- 1987 – ANSI Z34.2
- 1992 – ANSI conforms to international policies and procedures
- 1996 – ISO/IEC Guide 22
- 2004 – ISO/IEC 17050

Benefits

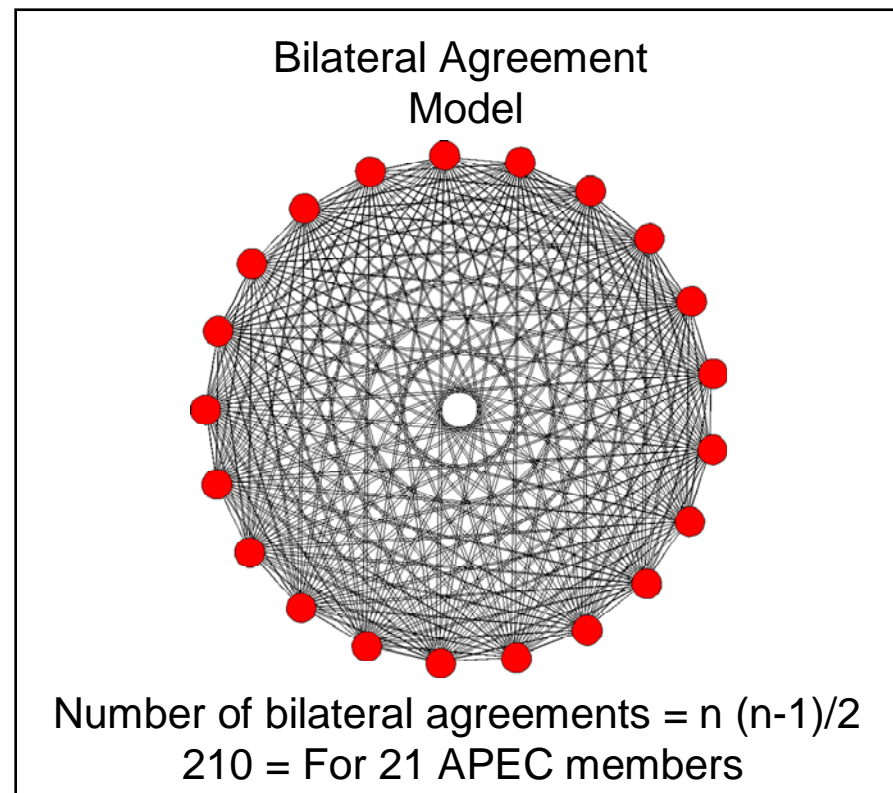
- Private sector
 - self-regulation
 - Market-value enhancement
- Govt. Agency
 - Purchasing and regulatory compliance
 - Cost-effective

Regulatory Benefits

- Simplifies administrative requirements
- Puts schedule under mfgr's control

SDoC and Post-Market Surveillance Preferred

IF each of the 21 APEC member economies mandated unique third-party certification and pre-market requirements 210 bilateral agreements needed to facilitate trade.



Disadvantages

- Non-compliance
- Foreign certification requirements for market access

Solutions



- 1992 – ANSI certification programs consistent with international standards
- Mutual recognition agreements with foreign national accreditation systems
- Priority on world-wide acceptance of US performed certifications
- Accreditations/certification marks

Enforcement

- Continuing surveillance
- Review substantiating docs for signs of trouble
- Enforce penalties for non-compliance
- As effective as pre-market requirements

Value

- Confidence in the product

Self-Certification

- Simplifies the certification process
- Reduces manufacturing costs
- Is somewhat self-policing
- Can be supported by regulation/enforcement
- Ease procurement/reduce lead times