English version

2003-1-14

Status Report on Framework for Standards Conformity Assessment and Consideration on Its Reform

November 2002

Conformity Assessment System Committee、

Japan Electronics and Information Technology Industries Association

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Part II Consideration on Reform of Conformity Assessment Framework

Reference

Foreword

JEITA (Japan Electronics and Information Technology Industries Association) represents its member companies making up the second largest industries in Japan, following the automobile industry, with electronics and information technology equipment, their parts and devices. As a leader of Japanese industries whose business is globally deployed in the world ever getting economically borderless, the association commits to fulfill its solid mission to provide safe and reliable products at reasonable prices that meet regulatory requirements of a given country.

Turning to business environment, on the other hand, customer requirements are diversified as product technology becomes more sophisticated and multi-function-oriented while it accelerates shortening of product life cycles. JEITA member companies are facing constant pressure to improve their constitutional characteristics and streamline their mode of operations to agilely cope with such environment changes.

In this business climate conformity assessment systems on products and systems of various countries including Japan, may they be of regulatory or voluntary nature, have a propensity to become excessive in requirements and repetitious in application if not run with care, which increase the cost of products and their administration. In addition conformity assessment systems can be one of factors to impede timely market access and free trades. Having recognized such problems involved in conformity assessment considerably impact business of member companies, JEITA established “Conformity Assessment System Committee” in 2001 for the primary purpose of realization of conformity assessment framework which is reasonable and reliable meeting needs of member companies. In order to accomplish this purpose it is first necessary to level members’ understanding of basic mechanisms and notions of conformity assessment system, portray an ideal one, and then to propose the idea to related parties.

The purpose of this paper is to explain fundamentals of conformity assessment framework for product safety, EMC and Quality Management System, clarify identified problems involved with current systems, and to facilitate coherent committee activities in pursuing the most desirable conformity assessment system for JEITA and its member companies.

Each ingredient of conformity assessment system this paper discusses does not stay still. Therefore, it is necessary to periodically revise the content as appropriate not to

get it outmoded. We hope this paper will serve us all as a guidebook in our policy formulation and outreach activities without being at the mercy of the tide of conformity assessment system in the world. (November 2002)

Summary

What is conformity assessment? (item I-1)

Need for reform of conformity assessment framework (item I-2)

- Growing awareness of value of WTO/TBT
- Global trend toward deregulation
- Problems of unreasonable conformity assessment
- Sophistication of assessment techniques going with new technology development
- Optimization of company's resources allocation for conformity assessment work

Reformative activities of related groups and organizations (item I-3)

- 2nd systematic review of WTO/TBT
- Deliberative activities on standards and rules in ISO/IEC
- Japan domestic deliberative framework for international harmonization
- International alliance of certification bodies and industry cooperation
- Japan domestic legislative arrangement and regulatory reform

The current status and problems of conformity assessment systems (item I-4)

- Timely market access is impeded in not a small number of countries with regulation for mandatory testing and certification.
- Existence of non-harmonized technical regulations and standards in different countries prevents global distribution of products.
- International certification and accreditation environment is only poorly created which facilitates the acceptance of a single assessment result anywhere.
- Competency gap widened between conformity assessment bodies as the number of them increases.
- Multiple sector specific QMS standards intensify burden of audit and registration on companies.
- Many marks with different purposes on a product confuse and mislead the customer.

Steps for reform of conformity assessment framework (item II-2)

Engagement for reform of conformity assessment framework (item II-3)

ISO/ CASCO

IEC/ CAB

ICSCA

GPCAS

- Examine values of conformity assessment
- Advocate deregulation
- Promote streamlined conformity assessment activities
- Secure reliability and transparency of conformity assessment
- Consider effective involvement of third party assessment bodies
- Fulfill the accountability for the validity of assessment results

What is reasonable conformity assessment? (II-1)

- For system developers: Systems with transparency and impartiality are widely used
- For companies: One assessment result based on one standard is passable worldwide
- For customers: Safe, reliable and inexpensive products and services are provided
- For regulatory authorities: Take reasonable legislative and administrative measures based on “Good Regulatory Practice”
- For conformity assessment bodies: Provide cost effective conformity assessment services

Part I: Current Status on Conformity Assessment Framework

1. What is conformity assessment?

ISO/IEC 17000 CD defines “Conformity Assessment” as ”activity or activities related to demonstrating whether or not an object of conformity assessment fulfills or continues to fulfill specified requirements” where an object of conformity assessment is either of product (or service), process, system, person or organization. “Specified requirement” means technical/system standards against which the conformity is assessed.

Conformity assessment activities, if analyzed in detail, can be broken down into the following four elements depending on the nature of conduct and performer.

① Conduct to ***inspect/test/audit*** the subject product and system

② Conduct to ***certify*** the positive result of attestation with inspection/testing/auditing

③ Conduct to ***accredit*** competency of inspection/testing/auditing-registration bodies and certification bodies

④ ***Aptitude of persons*** to perform conduct ① - ③

Conformity assessment activities viewed from the attestation scheme, on the other hand, can be categorized into the following three types depending on “by whom the assessment is performed.”

① Scheme of ***Supplier's Declaration of Conformity*** (SDoC) in which the supplier of the product (first party) himself performs the assessment and declares the conformity

② Scheme of ***Confirmation Between First and Second Parties*** in which the customer (second party) performs the assessment of the conformity from a purchaser's point of view

③ Scheme of ***Third Party Certification*** in which a qualified neutral body (third party) independent of the supplier and customer performs the assessment of the conformity

Viewed from the angle of whether or not conformity to a given requirement is legally regulated, conformity assessment activities fall into either of the following two fields.

(1) Regulated field

This is the filed, as typified by product safety and EMC, in which conformity assessment is regulated by law for safety and health of the user and the common good. Suppliers are legally bound to meet the requirement.

(2) Voluntary field

This is the field, as typified by management systems audit and registration with ISO 9001 and ISO 14000, in which conformity assessment is performed to add values to company's business or to meet the requirement of trade partners although doing so is not mandatory with few exception.

Based on the above information pigeonholed, main stakeholders involved with conformity assessment can be mapped as in the following chart.

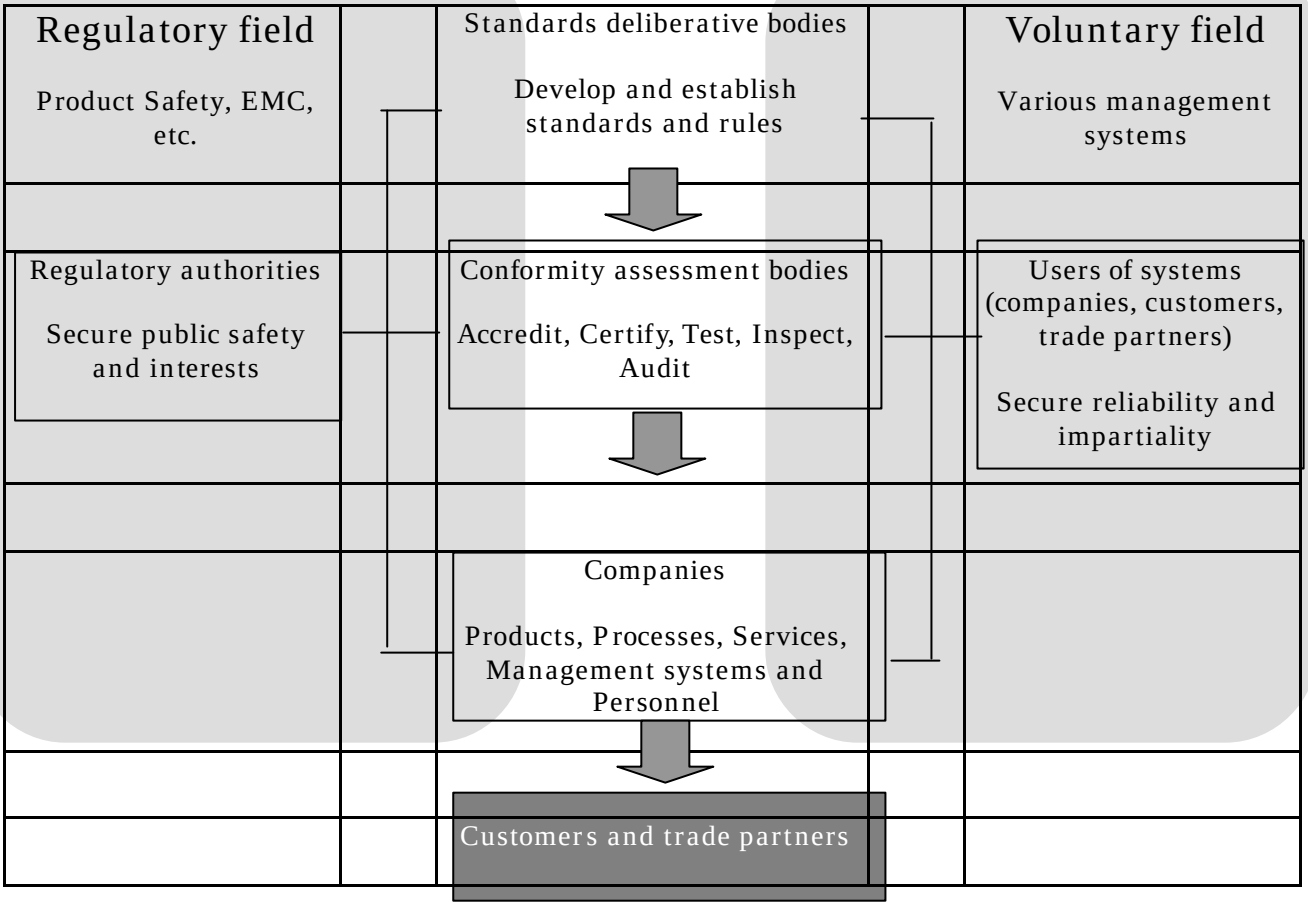


Figure I-1 Main stakeholders affecting conformity assessment

2. Need for reform of conformity assessment framework

Conformity Assessment is a basic engagement for a company to abide by law without fail in the regulatory field and to smoothly carry out business in the voluntary field. For many years in the past companies have been passively following a given conformity assessment system, which was established elsewhere without their involvement, to achieve their business purposes. In these days, however, as changes have taken place in socio-economic and technological environment, companies are increasingly required to actively pursue streamlining and improving conformity assessment framework for themselves. In what follows some of those changes are discussed.

(1) Awareness has has been increased in the industry that it is inevitable to take advantage of international standards on technical requirements and conformity assessment for the facilitation of freer global trade as the WTO/TBT agreement encourages.

(2) Deregulation occurring in many places in the world has shed light on the necessity to increase company's self-accountability. Also preparedness for possible product liability litigation is becoming increasingly demanding within a company. Under such circumstances there is every indication among all stakeholders that they should pursue reliable conformity assessment scheme in concert with each other.

(3) Deregulation at the same time can bring about excessive competitions on a global basis among private testing laboratories, certification bodies and audit and registration organizations, which will possibly degrade their service quality. Under such circumstances it has become necessary to revisit merits and demerits of commercialism of conformity assessment services in free competition and to possibly take countermeasures.

(4) The inclination to commercialism is observed markedly in the voluntary field typified by management system audit and registration. Increased burden on companies with questionable value addition brought about by periodical and duplicated audit resulted from expanded application of management system standards.

(5) The number of cases is on the increase in which proof of conformity to international standards is required as one of tender conditions for public procurement.

(6) Management in business climate ever getting stringent cannot afford not to

optimize resource allocation for conformity assessment activities

(7) Accelerated pace of technical development in electronics and information technology equipment necessitates fast self assessment of conformity without getting dragged out by the involvement of third parties.

(8) As packing density and digital sophistication of products continue to be magnified, requirements on product testing technology and its reliability are getting stringent.

Socio-economic climate changes such as reviewed above will no longer allow companies to continue long practiced passive conformity assessment activities by blindly following a given requirement. At this juncture companies cannot afford not to pursue conformity assessment schemes to yield maximum values at minimum cost.

3. Reformative activities of related groups and organizations

The fundamental principle of the WTO/TBT agreement that says, "Conformity assessment procedures should not create unnecessary obstacles to international free trades" is extensively affecting standardization activities at international level, regional and country level and industry level. The following is some of movement observed in various fields.

3.1 Second triennial review of the WTO/TBT agreement

A predecessor of "Agreement on Technical Barriers to Trade" was originally negotiated during 1973 – 1979 GATT Tokyo Round. It was enhanced and refined during 1986 – 1994 Uruguay Round, which was then taken over in the present name by WTO established in 1995. The agreement on TBT has been instrumental in preventing conformity assessment procedures of member countries from creating unnecessary obstacles to trade by promoting the use of international standards, encouraging to secure transparency of procedures and discouraging unfavorable treatment of imports.

At the second triennial review of the agreement done in November 2000 the following principles were newly adopted, which are influencing activities of various organizations working on international standards and rules in many ways.

(1) Pursuance of further transparency, openness and fairness in the process of international standards development

(2) Pursuance of market relevance of international standards (not to impede market

competition and technological innovation)

3.2 Deliberative activities in ISO/IEC

The following are major deliberative bodies for standards and rules on conformity assessment.

- ISO/CASCO: Responsible for the establishment of ISO/IEC guides and standards on conformity assessment
- IEC/CAB: Responsible for the management of conformity assessment systems such as IECEE-CB scheme

ISO/CASCO's current major undertaking is to revisit existing guides and standards for necessary revision in response to general requirement to enhance market relevance of standards in the environment in which awareness of the WTO/TBT agreement is raised in practicing conformity assessment. On the IEC side CMC (Certification Management Committee) under IEC/CAB is leading activities to expand the membership of IECEE – CB scheme, widen its scope to cover new fields including EMC, reexamine CB-FCS (Full Certification Scheme, a scheme for mutual recognition not only the result of type testing but of factory inspections), and study FAP (Factory Audit Program). Since the work of these deliberative bodies will considerably affect conformity assessment activities of the industry, the industry is expected to positively make its proposals.

3.3 Movement in Japanese domestic deliberative framework

In the past "Accreditation and Certification Committee" under the Japanese Industrial Standards Committee (JISC) handled conformity assessment related standards vis-à-vis ISO and IEC with Industrial Science and Technology Policy and Environment Bureau of Ministry of Economy, Trade and Industry as the secretariat. In November 2000 JISC issued a report titled "Basic direction on conformity assessment system in Japan," based on which JISC newly established "Conformity Assessment Committee" in 2001 opened for industry participation. Substantial work was commissioned to ISO CASCO Subgroup (WG1) and IEC/CAB Subgroup (WG2) under "Conformity Assessment Study Committee" facilitated by the Japanese Standards Association (JSA). There brisk discussions take place to formulate national position on the matter.

3.4 Mutual international cooperation between accreditation bodies

In order to promote mutual recognition of the result of “accreditation,” one of key ingredients of conformity assessment system, various accreditation bodies created cooperation groups and fora in alliance with each other. Appropriate operations of accreditation and international harmonization of accreditation criteria are among subjects for discussion in them. ILAC (International Laboratory Accreditation Cooperation) that deals with test laboratories is one of representative organizations of such groups, and another is IAF (International Accreditation Forum) that deals with management systems audit and registration bodies.

Leveraged by the movement associated with the TBT agreement and by ISO/CASCO’s undertaking on new conformity assessment standards, both federations are reasserting their presence by strengthening collaboration among member organizations and increasing their influence in the regulatory field.

3.5 International industrial cooperation for conformity assessment

Multi-national companies and industry associations of the U. S. and Europe allied to establish ICSCA (Industry Cooperation for Standards and Conformity Assessment) in 1996 for the purpose of taking initiatives in advocating “rational way of conformity assessment” against organizations having a stake in the matter. ICSCA is positively engaged in the formulation in a cross-industry fashion of influential opinions from a perspective of the user of conformity assessment systems. In 2001 six major Japanese companies and CIAJ (Communication and Information network Association of Japan) joined the group and are now participating in discussions on the evaluation of various standards and systems.

In concert with activities of ICSCA, companies in the telecommunication industry mostly of the U. S. and Europe united in issuing so-called Green Paper to the world in 2000. This paper advocates the concept of GPCAS (Global Product Conformity Assessment System) that stands on SDoC and market surveillance functions to be implemented worldwide. CIAJ participated in the campaign and now JEITA is being invited to the group.

These activities are considered to be instrumental in creating a cooperative climate between industry associations that need reasonable regulatory reform for the

promotion of industry and trades, regulatory authorities and conformity assessment bodies.

3.6 Arrangement of Japanese domestic laws and regulatory reform

“Three Year Plan on Regulatory Reform” formulated by the cabinet in March 2001 orders the implementation of reform of conformity assessment systems stipulated by statute. The following is an excerpt of the basic policy of it.

“In reviewing conformity assessment systems it is essential to extensively examine the justification for retention of the system as the one that has dependency on the involvement of the government. If judged not justified, the involvement of the government must be kept minimal by shifting the system to the one based on self verification and self safety assurance while promoting harmonization of standards with international ones, alteration of standards to performance oriented ones, avoidance of duplicated inspections and others…..”

Laws and ordinances that affect JEITA are under review in accordance with this direction.

4 The current status and problems of conformity assessment framework

Various brisk activities in the front of related field as reviewed above are welcome to us because they create opportunities to voice industry's opinions. However, if the current status is shed light on, it becomes apparent that there are many problems standing against industry's needs irrespective of where they exist, in Japan or abroad. Through positive activities of proposing solutions to the problems enumerated below one by one we will know we have paved the way for a better world for all stakeholders.

4.1 Statutory problems

Not a small number of countries have mandatory conformity assessment systems established and operated by law. In those systems regulatory authorities designate conformity assessment bodies and mandate them to perform assessment and certification through legalized processes. This scheme is referred to as compulsory certification system. While this system is convenient in a sense as responsibility for conformity is delegated to the authority, it causes a great loss of time and money on the

company in deploying the same product globally because it is inevitable for the company to take necessary measures required by law country by country as requirements are not harmonized for the most cases.

The following are concrete problems identified.

(1) Regulatory requirements and procedures released by the authority oftentimes lack clarity and transparency, which causes a great loss of time for information collection.

(2) The availability of testing and certification bodies is limited in number and geography, which prolongs the period to obtain certification. This immediately translates into delay of market access.

(3) Methods and procedures of conformity assessment are bureaucratic and inflexible as they are stipulated by law, which impede authority's acceptance of proposals on the improvement of the system including recognition of the result of testing and certification done elsewhere because such changes need onerous revision of the law.

(4) Regulatory framework of a given country is oftentimes unique to that country, which complicates efforts to promote global adoption of international standards and systems.

(5) Unique conformity assessment system of a country creating non-tariff trade barriers is prone to be politically used for the protection of domestic industry of the country in the disguise of protection of the consumer.

4.2 Problems of standards

Standards are ordinarily categorized into those on product specifications and management systems subject to assessment and those on practices and operations of conformity assessment.

The former group includes IEC 60065, IEC 60950, CISPR 13, CISPR 22 and ISO 9001. We have been advocating the importance of adoption of these standards to various parties concerned in Japan and abroad and see a certain result of it. Overall situation is promising in this area as indicated by the fact that even some of countries not a member of international standards organizations adopted these standards. However, there still are problems persisting in some countries as described in the following.

1) Little or no opportunities are open to the industry to have its requirements reflected in national standards because they are established on the initiative and control of government regulators and their designated committees.

2) In some countries there exist national differences and additional requirements unique to the country or region in their technical standards not in support of the environment in which products are used.

3) The timing of transposition of international standards into national standards and timing of their revision to meet the latest versions vary from country to country. This lack of simultaneity impairs common product design as it will result in non-compliance in certain countries while it will pass in other countries

4) Processes for establishment and revision of international standards are elongated, which creates void in standards on new technologies not covered by existing standards. This void then brings about disparity in the result of conformity assessment country by country and organization by organization.

5) In certain fields of product such as display and in quality management systems the industry oftentimes establishes its unique standards not harmonized with international ones. Those industry standards are used as a condition in trades and procurement imposing additional burden on suppliers.

As to the latter, namely, the standards on practices and operations of conformity assessment deliberated by ISO/CASCO and IEC/CAB, industry's presence in committee activities for their establishment is far from being substantial. The following are problems identified in this area.

1) Standards are established on the initiative of conformity assessment bodies in processes not transparent to the industry, the user of standards.

2) While some of norms established by ISO/CASCO as "ISO/IEC Guides" are being revised into "ISO/IEC International Standards," many remain as guides that are inclined to leave room for different interpretations of them.

3) Since those standards are designed to cover a wide area, they are versatile in

nature. On the other hand, however, they are not as serviceable as they should because there are many arguable abstract rules and provisions.

4) Speed to establish and revise standards is too slow to meet the needs of the industry in dynamically changing business climate.

4.3 Problems of systems and procedures

Conformity assessment systems and procedures, regardless of whether they are of regulatory field or of voluntary field, largely differ from country to country and from organization to organization. Such disparity comes from the choice of third party assessors and their interpretation of standards, and the choice of scheme to prove conformity, namely SDoC or compulsory certification, and from other factors. These diversified circumstance in conformity assessment present major challenges to companies struggling to win streamlined conformity assessment system without going through repetitious processes and thereby to provide the customer with reasonably priced products and services. What follows argues some of impediments identified.

1) A company's internal standards on product safety, for example, are usually set at higher level than those stipulated by regulations as the result of company's incessant efforts for improvement. For such companies a series of activities on conformity assessment is a factor to increase administration cost which translates into price increase of end products without adding any values to products and services.

2) In case of third party certification systems one of the reasons why one assessment result is not passable in the world is that certification bodies vary in their grade of facilities and level of personnel's competency among others.

3) Test laboratories accreditation systems in the voluntary field such as ILAC and APLAC are not adequately used in the regulatory field, which oftentimes calls for duplicated efforts in laboratories accreditation.

4) There is no common set of rules with which to certify factory quality management. If there is a local set of such rules, most likely it is enforced any way as a means to certify continuous conformity with the rules even when the

factory in question is already certified with ISO9001.

5) Rules for factory surveillance (inspection or audit in case of ISO 9001) by a third party are inflexible and not designed to afford an incentive to excellent companies.

6) There are little or no globally harmonized conditions for issuance of SDoC although ISO/CASCO has started working on standards addressing the need. Also there is no established method of outreach to the customer on the value of SDoC.

7) In case of product certification such as on safety and EMC, certification bodies make it a practice to grant the applicant right to label the product with a logo mark of the issuer as “a proof of approval.” Problem is, a product comes to bear multiple marks on it, which gets consumers confused and misled.

8) In some countries market surveillance system employed either by government regulators, certification bodies or voluntary organizations to monitor the compliance of products in the market are not necessarily enforced adequately

Table I-1 presents the current status on conformity assessment practices and their problems on product safety, EMC and Quality Management System.

Table I-1 The current status on conformity assessment practices and their problems

	Frame of reference	Product Safety	EMC	Quality Management System
Current status on conformity assessment systems	Regulated by law?	●Yes, in almost all countries and regions	●Yes, in most of industrialized countries	●No, except in few countries
	Regulatory authorities are involved in	●Defining technical requirements ●Deciding on CA schemes and appoint CA bodies ●Monitoring conformity of products distributed in the market	●Defining technical requirements ●Deciding on CA schemes and appoint CA bodies ●Monitoring conformity of products distributed in the market	●Adopting International Standards as national standards with translation
	Technical or system standards	●Unique ●Equivalent with IEC standards	●Unique ●Equivalent with IEC/CISPR standards	●ISO9001 standards ●Sector specific standards based on ISO9001
	Means to prove conformity with standards	●Certification obtained from a third party CA body designated by the authority ●Certification obtained from a third party CA body on a voluntary basis ●Manufacturer's declaration of conformity (SDoC)	●Certification obtained from a third party CA body designated by the authority ●Certification obtained from a third party CA body on a voluntary basis ●Manufacturer's declaration of conformity (SDoC)	●Audit and registration by a registrar on a voluntary basis
	Means of distribution and acceptance of assessment results	●Government-to-government MRAs (in case of compulsory system) ●MoUs between testing and certification bodies ●Use of IECEE-CB scheme	●Government-to-government MRAs (in case of compulsory system) ●MoUs between testing and certification bodies ●Laboratory accreditation based on ISO/IEC17025	●Cooperation between international and regional audit and registration bodies such as IAF, PAC and EA
	Means to prove sustenance of conformity	●Periodical factory inspections by certification bodies ●Self assurance	●Periodical factory inspections by certification bodies ●Self assurance	●Periodical audit by audit and registration bodies ●Periodical internal audit
	Means to communicate conformity to customers and public	●Label the product with a law-stipulated conformity mark ●Label the product with a certification body's logo or registered mark	●Label the product with a law-stipulated conformity mark ●Label the product with a certification body's logo or registered mark ●Attach declaration to the product or its manual	●Attach registered mark to product catalogues, brochures and visiting cards (attaching mark on product not allowed)

Major problems	●Regulatory practices differ from country to country where government certification is compulsory. ●Technical regulations differ from country to country or deviate from IEC standards ●On IECEE-CB scheme: -It is not much honored in compulsory certification system in countries ・There are big competency gaps between test laboratories ・Participation by developing countries is not brisk ・A factory inspection result is not accepted on a multilateral basis ●Proliferation of certification marks issued by different countries confuse customers	●Frequent revisions of International Standards impede global harmonization of technical requirements used in the field ●Assessment results issued by laboratories based on international or regional laboratory accreditation program are not widely recognized by governments with compulsory certification systems ●It is difficult to secure traceability of measurement results ●Manufacturers cannot help but rely on foreign laboratory accreditation bodies due to slow progress in domestic accreditation system ●Japanese regulatory environment: ・There coexist regulations by multiple government agencies and self control by voluntary organization ・Technical requirements and administrative procedures of the Electrical Equipment and Material Safety Law are not harmonized with international norms.	●System such as IAF for mutual acceptance of audit and registration results is immature. ●New sector specific standards developed one after another impose heavy burden on suppliers. ●Many different marks of audit organizations get general market confused. ●Periodical audit by audit and registration bodies is inflexible and its cost – performance is low. ●Aptitude and competency of auditors are uneven and their interpretation of standards is not coherent among them.

Part II: Considerations on Reform of Conformity Assessment Framework

1. What is reasonable conformity assessment?

No one will dispute the notion that an ideal and common goal of conformity assessment system for stakeholders, may they be system developers, companies, customers, regulatory authorities and conformity assessment bodies, either in the regulatory field or voluntary field, is to facilitate assessment in most effective manner at minimum socially affordable burdens. What follows discusses ideal conformity assessment system, or desirable situations brought about by it, for each stakeholder viewed from a perspective of a user of the system.

1.1 For system developers

- Criteria and rules for conformity assessment are deliberated and established in such a way that they contribute to the global facilitation of free distribution of products and services in line with the fundamental principle of WTO/TBT agreement.
- Such deliberation strikes balance between opinions of producers (standards bodies), providers (certification bodies) and users (companies and customers).
- Established criteria and rules for conformity assessment are transparent and impartial to be globally used irrespective of whether in the regulatory field or voluntary field.

1.2 For companies

- Only conformity assessment system is developed that meets the needs of companies and it is used by them on a voluntary basis.
- Conformity assessment system has the flexibility to adapt changes in the environment in which companies operate and in characteristics of products which they manufacture.
- To be empowered to streamline conformity assessment activities based on the “One standard – One mark – One certification” practice widely adopted in the world.
- The result of a single conformity assessment has trustworthiness regardless

of the country or region where the assessment is performed.

- Going through conformity assessment does not impede timely market entry of products developed with new technology.
- Cost of conformity assessment is proportionate to its purpose.
- Conformity assessment system best serves streamlining of conformity assessment practice done by the purchaser in trades between companies.

1.3 For customers

- The customer can enjoy the safety and reliability of products and services he purchases.
- Products and services he pays for do not include cost of conformity assessment activities that do not add any value to his purchase.
- He can do informed purchase via marking on the product regarding the conformity attested, which gives him the sense of security.
- When troubles occur, the customer is disclosed relevant information on the result of conformity assessment by the company.

1.4 For regulatory authorities

- To be able to assure safety, health and welfare of public through the introduction of reliable conformity assessment system.
- To have their legislative and administrative measures streamlined with the adoption of Good (Best) Regulatory Practice.
- To contribute to the growth of the domestic industry by securing global free trade environment with the introduction of internationally harmonized conformity assessment system in accordance with the WTO/TBT agreement.
- To retain the control of conformity with efficient and economical market surveillance mechanism introduced to verify the validity of assessment, and with salvation measures is in place for damages done by non-compliant products.

1.5 For conformity assessment bodies

- To win the trust of the customer (applicant) by providing highly valued and high cost-performance services.
- To build partnership with companies that decide to go with self verification.
- To have the result of their conformity assessment accepted by the rest of conformity assessment bodies in the world without getting overridden by re-assessment.
- To maintain advanced assessment technique and service price competitiveness with which to win through free competition between peer bodies.

2. Steps for reform of conformity assessment framework

First of all it is necessary for us to understand gaps between conformity assessment systems being practiced in the world and a desirable one we portray. Then we should prioritize target elements to grapple with towards final goal of the reform. Figure II-1 illustrates doable steps for this purpose taking into consideration the current status and future directions of the matter in the world.

It is important to grasp accurate situations in each sphere of conformity assessment system, namely product safety, EMC and quality management system because they differ from country to country and region to region.

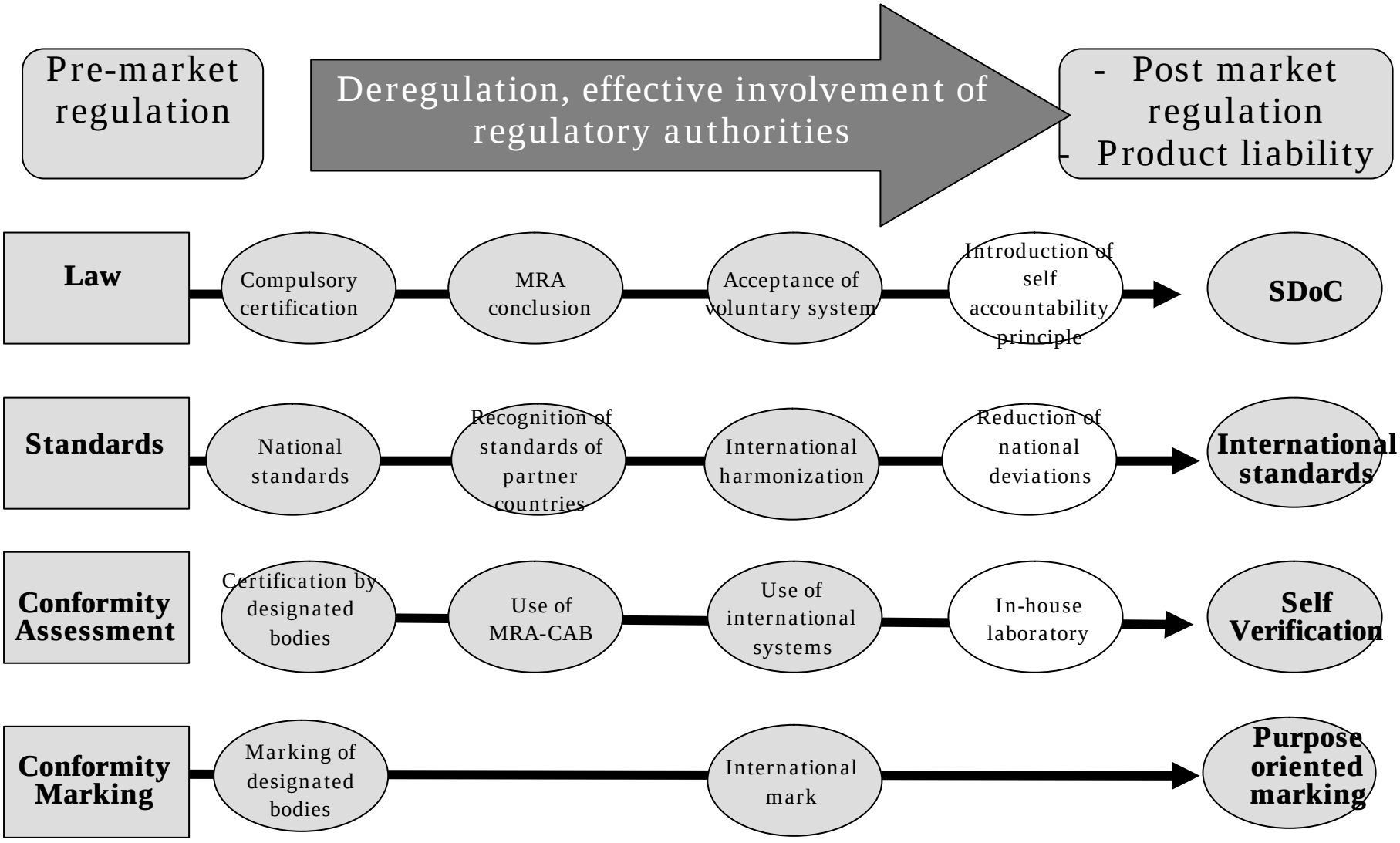


Figure II-1 An example of steps of reform from present situation to ideal one

3. Engagement for reform of conformity assessment framework

JEITA Conformity Assessment System Committee worked out proposed engagement for reform of conformity assessment framework as follows, which should be referenced in the future committee activities.

3.1 Examine the value of conformity assessment

In order to prevent conformity assessment systems not meeting user's needs from being proliferated in whichever field, regulatory field or voluntary filed, and to prevent profit-centered commercialism from sneaking in services provided by third parties, we are going to shed light on "ideal conformity assessment framework" that truly adds values for companies and customers, based on which we will make proposals to parties concerned as necessary.

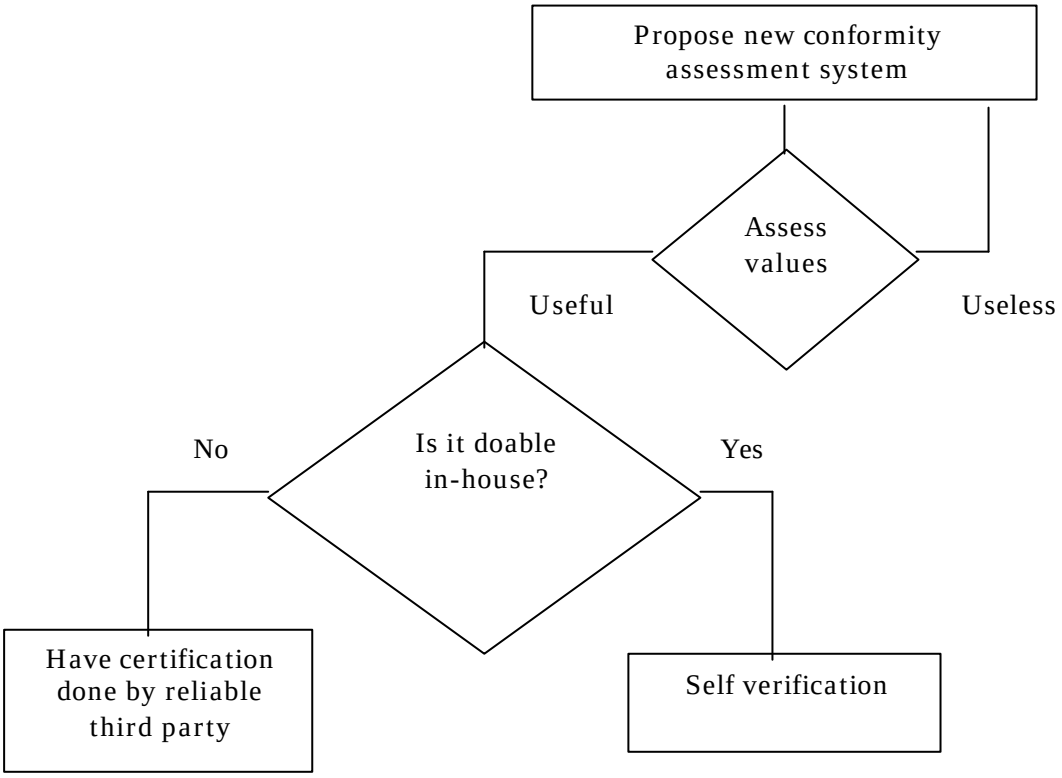


Figure II-2 An example of evaluation of conformity assessment system

3.2 Advocate deregulation

In order to win flexibility of conformity assessment in the regulatory field we are going to encourage regulators to minimize legislative involvement in procedures for conformity assessment, to rely more on international voluntary standards and rules, and to accept systems based on self accountability principle. Also we are going to study effective market surveillance scheme and damage salvation system from a perspective of a company.

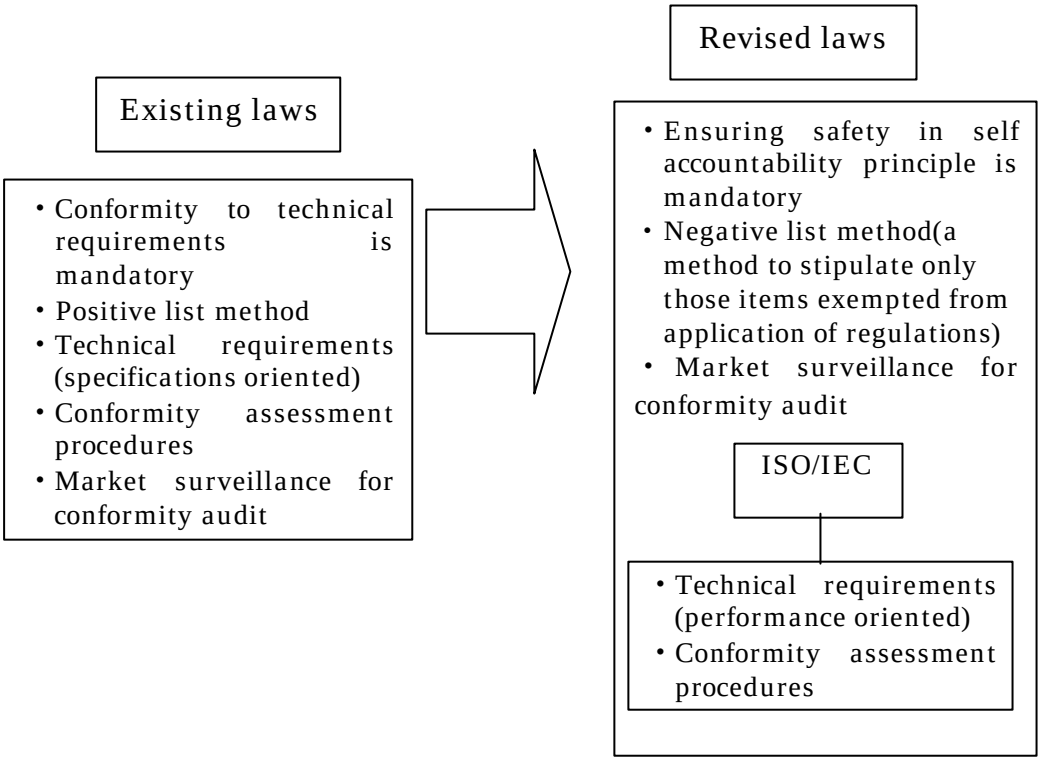


Figure II-3 An example of desirable legislative initiatives for regulatory reform

3.3 Promote streamlined conformity assessment activities

We are going to pursue the rationality of conformity assessment to achieve the following qualification as an objective. That is, assessment is done only once with high assessment quality and in cost effective manner, and the assessment result commands global acceptance which gets redundant assessment dispensed with.

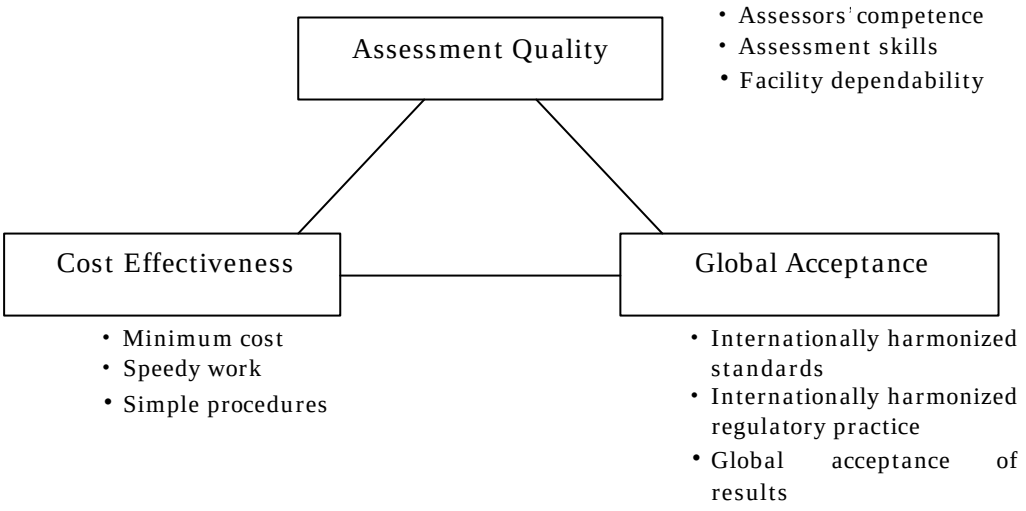
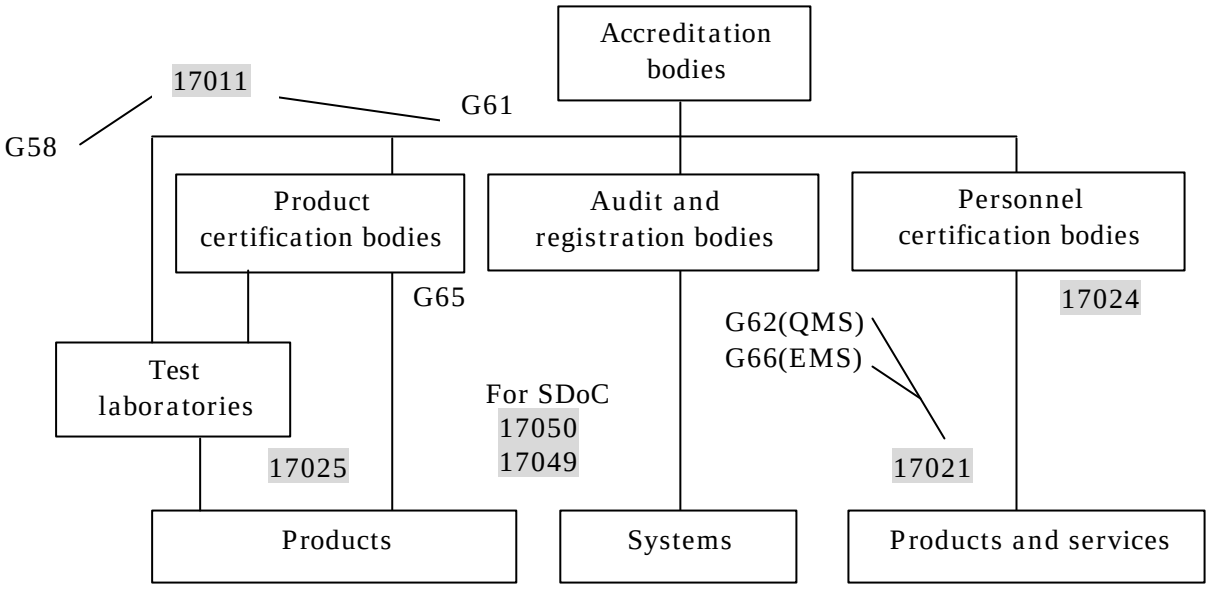


Figure II-4 Major three pillars for rational conformity assessment

3.4 Secure reliability and transparency of conformity assessment

We are going to pursue reliability and transparency of conformity assessment with the following standing as an objective. That is, each element of conformity assessment, namely inspection/testing, certification, accreditation and personnel, is harmonized with relevant ISO/IEC standards or guides established by ISO CASCO. For this purpose we will participate in related standards committees to voice industry's opinion.



Note: G58 means ISO/IEC Guide 58 and 17011 means ISO/IEC 17011 etc

Figure II-5 Major ISO/IEC Guides and Standards

Table II-1 indicates major ISO/CASCO documents on Conformity Assessment

3.5 Consider effective involvement of third party assessment bodies

While the law-enforced involvement of third parties in conformity assessment should be kept minimal, companies voluntarily use third party assessment bodies from time to time to validate the reliability of self performed assessment or to outsource the task. In order to make such engagement more effective and efficient we are going to consider effective and streamlined involvement of third party assessment bodies.

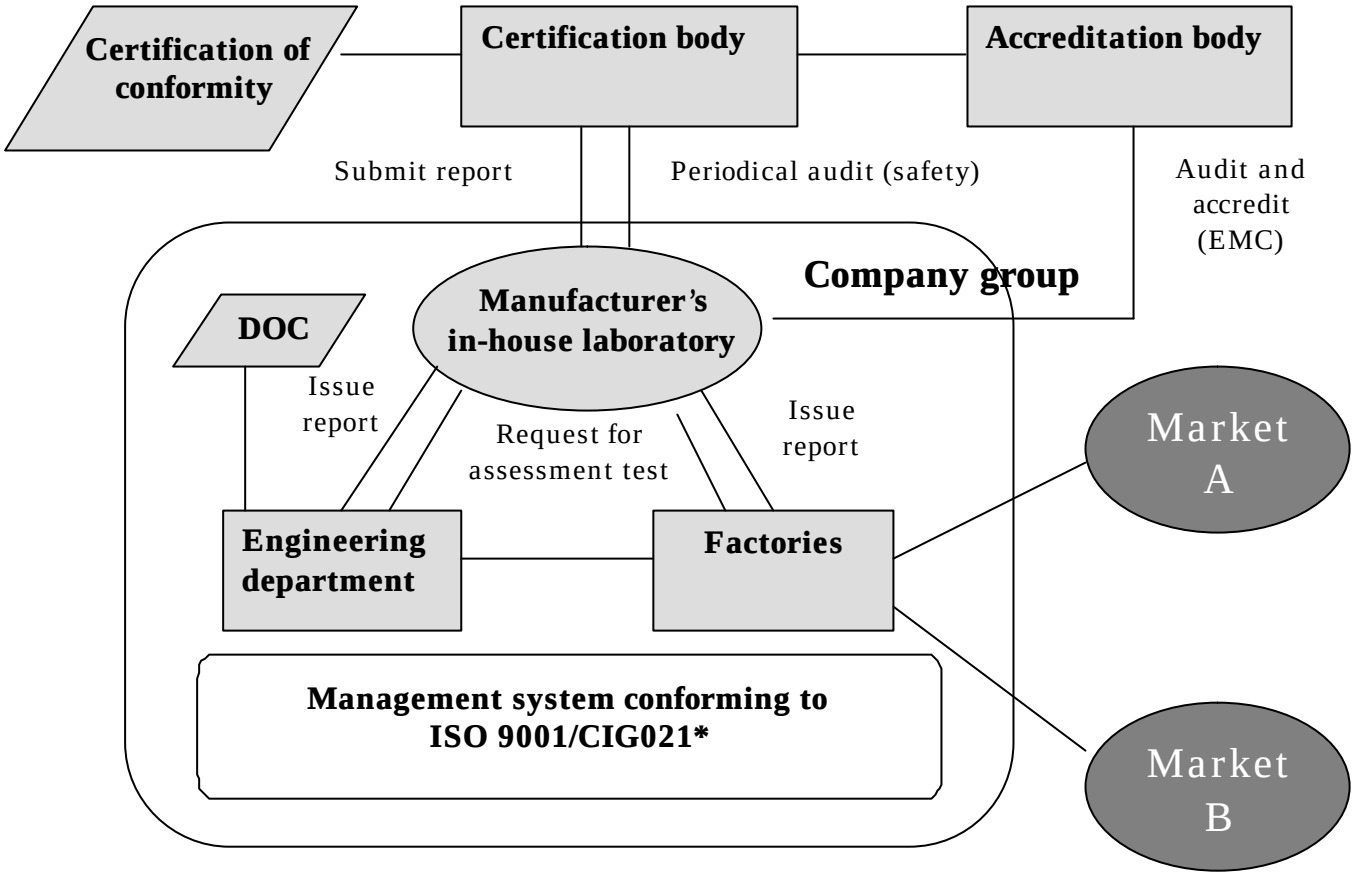


Figure II-6 An example of the involvement of third party certification bodies in manufacturer's self conformity assessment activities

* Note: CIG021 (factory inspection procedure) is a harmonized document of CENELEC CCA widely used not only in Europe but in other areas including Japan (for the S-mark system). Since there are no internationally applicable rules in factory management requirements for safety, it is referenced in this chart.

3.6 Fulfill the accountability for the validity of assessment results

We are going to establish and put into practice reasonable methods of documentation and retention of created documents with which to promptly demonstrate the validity of conformity assessment based on self accountability principle when requested by customers, trade partners and regulatory authorities.

Table II-1 tabulates concrete study items in each of product safety, EMC and quality management area for reform of conformity assessment framework.

Table II-1: Study items for reform of conformity assessment framework in each area

Frame of reference	Objectives of activities		
	Product Safety	EMC	Quality Management System
Regulations	●Abolish compulsory government or third party certification ●Replace specification oriented standards with performance oriented ones with reference interpretations that enable flexible implementation, and introduce self accountability principle ●Adopt voluntary systems on conformity assessment of ISO/IEC etc. ●Build effective post-market surveillance system		●Abolish audit and registration enforced by law in certain countries
Technical or system standards	●Get standards of every country harmonized with IEC/CISPR and synchronized with each other in the timing of introduction ●Minimize local deviations in every country		●Prevent proliferation of sector specific management system standards
Requirements on conformity test and audit	●Test laboratories (including first party's labs): To clear ISO/IEC 17025 ●Certification bodies: To clear ISO/IEC Guide 65		●Audit and registration bodies: To abide by ISO/IEC Guide 62
	●Accreditation bodies: To clear ISO/IEC Guide 58/61(ISO/IEC17011)		
Means to prove conformity with standards	●Adopt SDoC scheme based on ISO/IEC Guide 22 (being revised as 17050) ●Adopt standards on declaration supporting documentation (being developed as 17049) ●Use effective third party certification of supplier's choice to back up SDoC as necessary		●Adopt SDoC sheme ●Apply third party audit and registration as necessary
Means of distribution and acceptance of assessment results	●Facilitate free distribution and acceptance of results of assessment furnished by accreditation/certification organizations accredited with ISO/CASCO standards ●Expand international community of mutually recognized certification bodies with more members (enhance ILAC/IAF cooperation)		
	●Enhance IECEE-CB schemes with increased members and expanded field		
Means to communicate conformity to customers and public	●One symbol – one subject of conformity assessment on a type of product		●Unified QMS symbol
	●Create environment for the customer to freely access information on conformity assessment results		
Means to prove sustenance of conformity	●Combined implementation of product certification and factory inspection based on CB-FCS stepped up with MLA ●Conform to CIG201 safety management requirements		●Periodical audit by qualified internal auditors
	●Establish self-governed management system for conformity testing and mass production of products based on voluntary engagement with ISO 9001		

Domestic and overseas organizations to cooperate each other	●Domestic and overseas government agencies, accreditation bodies and testing and certification bodies ●ISO, IEC, CISPR and their domestic corresponding deliberation bodies, IAF, PAC, IATCA, ILAC and APLAC ●CIAJ, JEMA, JBMIA, ITI, EICTA, GPCAS, ICSCA		
Areas needing intensified initiatives	●Refresh One-One-One concept ●Propose the enhancement of IECEE-CB scheme and evaluate peer assessment scheme ●Study and examine domestic and overseas certification systems and propose the improvement of them as appropriate	●Study feasibility of One-One-SDoC scheme ●Study and propose IECEE-CB scheme expansion to EMC area ●Study domestic and overseas certification systems and evaluate them for proposal on necessary improvement	●Examine applicability of SDoC scheme to MSS ●Propose to narrow competency gaps between auditors ●Influence IAF/PAC to realize One-stop audit and registration ●Advocate unified symbol concept

Table II-2 Major ISO/CASCO documents on Conformity Assessment
(as of October 2002) Note: Items without year notation are under deliberation

1. Basic documents pertaining to the whole publication

ISO/CASCO Document numbers	Title	Remarks
ISO/IEC Guide 60:1994 WG22	ISO/IEC Code of good practice for conformity assessment	Under revision
ISO/IEC Guide 2:1996	Standardization and related activities- General vocabulary	
ISO/IEC 17000 WG5	Conformity assessment-Fundamentals and vocabulary	Guide 2 revised into IS
ISO/IEC Guide 70 WG5(TF)	Guidance for identifying first, second and third parties in conformity assessment	
ISO/IEC Guide 7:1994	Guidelines for drafting of standards suitable for use for conformity assessment	
ISO/IEC 17001 WG20	Guidelines for drafting of standards suitable for use for conformity assessment	Guide 7 revised into IS
ISO/IEC Guide 22:1996	General criteria for supplier's declaration of conformity	JIS Q 0022: 1997
ISO/IEC 17050 WG24	General requirements for supplier's declaration of conformity	Guide 22 revised into IS
ISO/IEC 17049 WG24	General requirements for supporting documentation for a supplier's declaration of conformity	
ISO/IEC Guide 23:1982	Methods of indicating conformity with standards for third-party certification systems	
ISO Guide 27:1983	Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity	
ISO/IEC Guide 68 WG11	Agreements for the recognition and acceptance of conformity assessment results	
ISO/IEC 17030 WG12	Third party marks of conformity and their use	
ISO/IEC 17040 WG19	General requirement for peer assessment of conformity assessment bodies	

2. Documents on accreditation bodies

ISO/CASCO document numbers	Title	Remarks
ISO/IEC Guide 58:1993	Calibration and testing laboratory accreditation systems- General requirements for operation and recognition	JIS Z 9358: 1996
ISO/IEC Guide 61:1996	General requirements for assessment and accreditation of certification/registration bodies	JIS Z 9361: 1996
ISO/IEC TR 17010:1998	General Requirements for bodies providing accreditation of inspection bodies	TR Q 0002: 2000
ISO/IEC 17011 WG18	General requirements for bodies providing assessment and accreditation of conformity assessment bodies	Guide 58, Guide 61 and TR 17010 combined into IS

3. Documents on testing and calibration laboratories and inspection organizations

ISO/CASCO document numbers	Title	Remarks
ISO/IEC 17025:1999 WG25	General requirements for the competence of testing and calibration laboratories	JIS Q 17025: 2000
ISO/IEC Guide 43-1:1997	Proficiency testing by interlaboratory comparisons – Part 1: development and operation of proficiency testing schemes	JIS Q 0043-1: 2000
ISO/IEC Guide 43-2:1997	Proficiency testing by interlaboratory comparisons – Part 2: Selection and use of proficiency testing scheme by laboratory accreditation bodies	JIS Q 0043-2: 2000
ISO/IEC 17020:1998	General criteria for the operation of various types of bodies performing inspection	JIS Q 17020: 2000

4. Documents on product certification

ISO/CASCO document numbers	Title	Remarks
ISO/IEC Guide 65:1996	General requirements for bodies operation product certification systems	JIS Q 0065: 1997
ISO/IEC Guide 28:1982	General rules for a model third-party certification system for products	
ISO/IEC Guide 53:1988	An approach to the utilization of a supplier's quality system in third party product certification	To be revised by an Ad-Hoc Group
ISO/IEC Guide 67 WG14	Fundamentals of product certification	

5. Documents on system audit

ISO/CASCO document numbers	Title	Remarks
ISO/IEC Guide 62:1996	General requirements for bodies operating assessment and certification/registration of quality systems	JIS Z 9362: 1996
ISO/IEC Guide 66:1999	General requirements for bodies operating assessment and certification/registration of environmental management systems(EMS)	JIS Q 0066: 2000
ISO/IEC 17021 WG21	General requirements for bodies providing assessment and certification of management systems(Part1), Specific requirements for bodies providing assessment and certification of Quality Management Systems(Part2), Specific requirements for bodies providing assessment and certification of Environmental Management Systems(Part3)	Guide 62 integrated with Guide 66 into IS

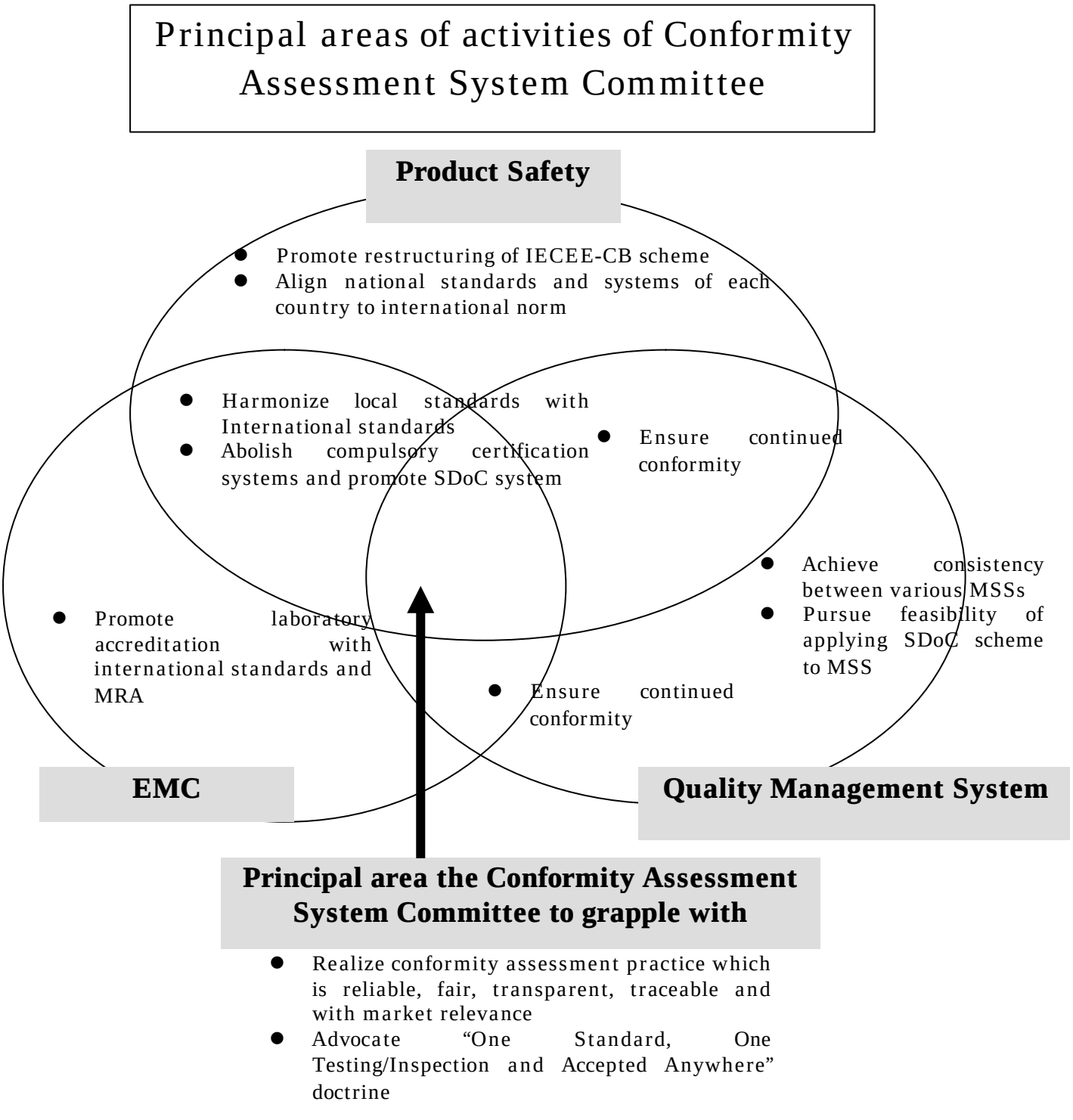
6. Documents on certification of personnel

ISO/CASCO document numbers	Title	Remarks
ISO/IEC 17024 WG17	General requirements for bodies operating certification systems of persons	EN 45013 transposed into IS

Reference

1. Scope of the JEITA Conformity Assessment System Committee

The Conformity Assessment System Committee was established in 2001 with an objective to advocate to related parties reform of conformity assessment framework for product safety, EMC and quality management system. The following chart illustrates its relationship with existing JEITA committees on product safety, EMC and quality management system.



2. Main engagement of the JEITA Conformity Assessment System Committee

(Excerpt from a report of the JEITA Environment and Safety General Committee)

Perform the following activities for opinion formulation and advocacy in the areas of accreditation, certification, testing, inspection and personnel qualifications, which are referred to as basic ingredients of conformity assessment. Covered area is the one that commonly concerns product safety, EMC and quality management system, each of which is handled in respective committees under the JEITA Environment and Safety General Committee.

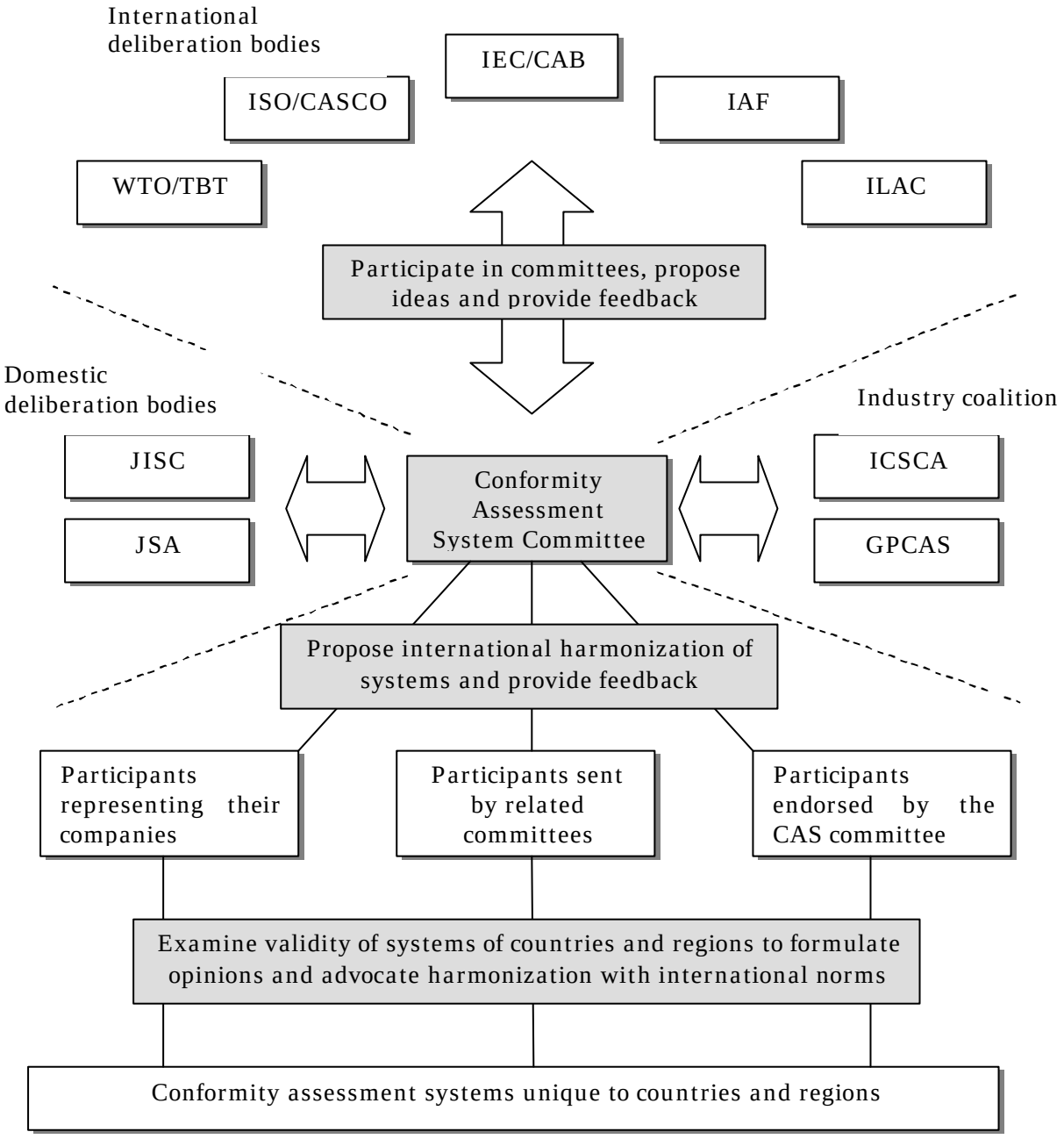
① Input industry positions to "Conformity Assessment Committee" and its subcommittees under JISC (Japanese Industrial Standards Committee) supervised by Ministry of Economy, Trade and Industries, and "Conformity Assessment Study Committee" of JSA (Japanese Standards Association)

② Directly or indirectly propose to international deliberation bodies responsible for conformity assessment matters such as ISO/CASCO and IEC/CAB.

③ Participate in and contribute to international industrial coalitions on conformity assessment matters such as ICSCA and GPCAS.

④ Discuss resolutions and directions of those committees and organizations and feed them back to member companies.

⑤ Lobby with individual countries and regions for alignment of their conformity assessment systems with international norms



A chart of concept on engagement relationship between JEITA Conformity Assessment System Committee and related committees