The proliferation of conformity assessment bodies

The language of EMC is becoming infused with terms for standards and certification groups.

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The word "body" is being used more frequently in the Conformity Assessment world as inspection, testing, standards and certification become more prevalent in the total economy of planet Earth. This article takes a look at the more common definitions of "bodies" being used in the United States, the European Union and elsewhere relative to EMC engineering.

Webster's fifth definition of "body" is "a group of persons or things; as
a: a fighting unit: force
b: a group of individuals organized for some purpose (a legislative body)."[1]

The second half of this definition is the term used in conformity assessment. A further clarification is found in ISO/IEC Guide 2-1986[2] which defines "body" as "a legal or administrative entity that has specific tasks and composition." It adds a further note that "examples of bodies are organizations, authorities, companies and foundations."

COMPETENT BODY

A Competent Body may be the most well-known "body" term in the area of EMC engineering in the United States. Competent Bodies are defined in Article 1 of the EMC Directive from the European Community.[3] Competent Body is defined as: "any 'body' which meets the criteria listed in Annex II and is recognized as such."

The Annex II criteria are:

- Availability of personnel and of the necessary means and equipment
- Technical competence and professional integrity of personnel
- Independence, in carrying out the tests, preparing the reports, issuing the certificates and performing the verification function provided for in this Directive, of staff and technical personnel in relation to all circles, groups or persons directly or indirectly concerned with the product in question
- Maintenance of professional secrecy by personnel
- Possession of civil liability insurance unless such liability is covered by the State under national law

Fulfillment of the conditions under points 1 and 2 shall be verified at intervals by the competent authorities of the member states.

In article 10.2 of the EMC Directive, Competent Bodies are given the responsibility of generating a technical report (or certificate) which must be included in the manufacturer's Technical Construction File (TCF).

Further clarification of this important definition is found in the "Guidelines" document from the European Union[4], in which it is stated that "Bodies which are

able to provide proof of their conformity with Annex II—through a certificate or other means showing compliance with the appropriate voluntary EN 45000 series of standards—are considered *competent* in the meaning of the EMC Directive." The "Guidelines" document states further that "a manufacturer's laboratory can be recognized as a Competent Body provided that it satisfies the criteria in Annex II and, in particular, provided that it can give assurances regarding its independence and impartiality from the design and production processes."

Competent Bodies "help the manufacturer" assess and declare conformity to the EMC Directive.

A Competent Body can be recognized as such by an Accreditation Body of Member State of the European Economic Area (EEA) or by a "body" representing the supervisory authority of a Member State of the EEA.

Footnote #48 of the "Guidelines" is very interesting and is repeated below:

> *Competent Bodies could limit the testing required by the manufacturer to what is essential for the purposes of the assessment of conformity, using their know-how related to the apparatus or systems. Often apparatus or systems are similar or very similar, from the EMC standpoint, to others already fully tested and certified. They can build upon such experiences and offer a cost-effective service, while maintaining full compliance with the directive.*

In other words, Competent Bodies can make exceptions to the letter of the law based on their experience and technical expertise!

CERTIFICATION BODY

A Certification Body is defined by EN 45020 to be a "body that conducts certification of conformity."[5] It further notes that "a Certification Body may operate its own testing and inspection activities or oversee those activities carried out on its behalf by other bodies."

Certification Bodies are both very formal organizations and very intrinsically European. They are less prevalent or even known in the United States. In Europe, Certification Bodies are recognized or accredited by European governments (member state governments). For example, in Germany, the Deutschen Akkreditierung Rat (roughly translated as the German Accreditation Body), also known as the DAR, certifies the capability of Certification Bodies.

Certification Bodies must comply with ISO/IEC Guide 65.[6]

Certification bodies may by certified for Quality Management Systems, for Product Certification, and for Certification of Personnel.

NOTIFIED BODIES

Notified Bodies must be "notified" to the European Economic Commission. They have expertise similar to that outlined in Annex II of the EMC Directive, but they may also be "notified" for telecommunications, medical devices and other technical areas.

For the EMC Directive, Notified Bodies are responsible for issuing the European Community-type examination certificates as referred to in Article 10.6 of the Directive. These EC-type examination certificates are required for Telecommunications Terminal Equipment and for apparatus designed for the transmission of radiocommunications.

Under the Medical Device Directive, Notified Bodies are also part of an exclusive club of knowledgeable and experienced entities that can qualify medical devices for use in the European Union.

TELECOM CERTIFICATION BODY

A Telecom Certification Body (TCB) was defined in the United States Federal Communications Commission Notice of Proposed Rulemaking released May 18, 1998, GEN Docket 98-68, FCC 98-62.[7] TCBs are private organizations that can test equipment as an alternative to certification by the FCC, and they can also grant certification to telecommunications equipment.

International Standards Organization (ISO) / International Electrotechnical Commission (IEC) Guide 65 (1996), General Requirements for Bodies Operating Product Certification Systems has been proposed by the FCC as the criteria to be met by a TCB. This Guide 65 basically requires:

- Impartiality
- Responsibility for their decisions
- Quality system
- Personnel with knowledge and experience relating to the type of work performed
- Documentation for the certification system
- Maintenance of approval records
- Performance of internal audits
- Performance of post-market surveillance

In addition to these general requirements, additional specific requirements will be required:

1. The TCB must demonstrate expert knowledge of the regulations for each product with respect to which it seeks designation. (Such expertise must include familiarity with applicable technical regulations, administrative provisions or requirements, as well as policies and procedures used in the application thereof.)

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2. The TCB should have the technical expertise and capability for testing the equipment it will certify and must also be accredited in accordance with ISO/IEC Guide 25 to demonstrate it is competent to perform such tests.
3. The TCB must demonstrate an ability to recognize situations where interpretations of the regulations or test procedures may be necessary. (Appropriate key certification and laboratory personnel must have the requisite knowledge of how to obtain current and correct technical regulation interpretations.)
4. TCBs must make a commitment to participate in any consultative activities identified by the FCC to establish understanding and interpretation of applicable regulations.

INSPECTION BODY

An Inspection Body is an independent impartial body having the organization, staffing, competence and integrity to perform inspection services to specified criteria. Inspection services are understood to include such functions as assessing, recommending for acceptance and subsequent audit of suppliers' production and testing facilities, personnel and quality control operations, and selection and evaluation of products on-site or in factories, laboratories or elsewhere as directed.[8] An Inspection Body should clearly define the areas of technology to be covered by its inspection services and for which it is qualified.

Inspection Bodies may be formally recognized by other Bodies. This "recognition" signifies a formalized judgement that the Inspection Body has demonstrated an acceptable level of competence in providing inspection services.

STANDARDS BODY

A standardizing body recognized at the national, regional or international level, that has as a principal function, by virtue of its statutes, the preparation, approval or adoption of standards that are made available to the public is called a Standards Body.[2]

LABORATORY ACCREDITATION BODY

A Laboratory Accreditation Body is one which conducts and administers a laboratory accreditation system and grants accreditation. A Laboratory Accreditation Body may wish to delegate, fully or partially, the assessment of a laboratory (testing or calibration) to another assessment agency. Such assessment must be equivalent to that applied by the Laboratory Accreditation Body and the original Laboratory Accreditation Body shall take full responsibility for such extended accreditation.

CONFORMITY ASSESSMENT BODY

Aside from evaluating conformity, conformity assessment involves "any activity concerned with determining directly or indirectly that relevant requirements are fulfilled."[2] Typical examples of conformity assessment activities are sampling, testing, inspection, evaluation, verification, assurance of conformity through a supplier's declaration or certification, registration, accreditation, and approval (as well as their combinations).

The United States–European Community Mutual Recognition Agreement (MRA) uses the term Conformity Assessment Body (CAB) to designate organizations that are qualified to participate in the areas of EMC, telecommunication terminal equipment, electrical safety, and medical devices. The transitional phase of the US-EC MRA began December 1, 1998 when the two groups exchanged lists of potential CABs with one another.

The National Institute of Standards and Technology, a major department of the United States Department of Commerce, used the following criteria to evaluate potential CABs to be nominated to the European Commission:

1. Must be located in the United States
2. Must be accredited by a recognized accreditation body that meets ISO/IEC Guide 58[9] or ISO/IEC Guide 61[10] and accredits to ISO/IEC Guide 25[11] or ISO/IEC Guide 62[12] for the sectors covered under relevant MRA annexes
3. Must provide detailed information on its current scope of competence, including specific standards and test methods relevant to MRA sectors
4. Must demonstrate familiarity/experience with conformity assessment procedures related to relevant EU directives

These criteria were published in the Federal Register, Volume 61, No. 89, May 7, 1996 p. 20513.

It is interesting to note that under the provisions of the EMC Sectoral Annex, NIST is nominating potential United States CABs to perform the functions of Competent Bodies under the EMC Directive of the European Community!

SUMMARY

This article summarizes some of the key Bodies in the Conformity Assessment world. There are many other Bodies around the world and we may see further developments of this word "Body" in the future. There may be a time when even politicians adopt the word, as did the governor of Minnesota, Jesse "The Body" Ventura!

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