

October 20, 2000

Ms. Magalie Roman Salas  
Secretary, Federal Communications Commission  
Room TW-A325  
445 12<sup>th</sup> Street SW  
Washington, D.C. 20554

Re: Ex Parte, In the Matter of Notice of Proposed Rulemaking (NPRM) in Docket No. CC 99-216, In the Matter of Biennial Regulatory Review of Part 68 of the Commission's Rules and Regulations (47 C.F.R. Part 68)

Dear Ms. Salas:

This is to confirm that on October 20, 2000, the Information Technology Industry Council (ITI) and the Telecommunications Industry Association (TIA) User Premises Equipment Division participated in a meeting with L. Charles Keller, Chief, Network Services Division (NSD), Common Carrier Bureau (CCB); Staci L. Pies, Deputy Division Chief, NSD, CCB; Julius Knapp, Chief, Policy and Rules Division, Office of Engineering and Technology (OET); Geraldine Matise, Deputy Chief, Policy and Rules Division, OET; Art Wall, Engineering Advisor, Policy and Rules Division, OET; William Howden, Commission staff engineer, CCB; and Dennis Johnson, Attorney Advisor, NSD, CCB; to discuss Notice of Proposed Rulemaking (NPRM) in Docket No. CC 99-216, In the Matter of Biennial Regulatory Review of Part 68 of the Commission's Rules and Regulations (47 C.F.R. Part 68).

Participating in the meeting, in addition to L. Charles Keller, Staci L. Pies, Julius Knapp, Geraldine Matise, Art Wall, William Howden, and Dennis Johnson were John Godfrey and William Johnson, ITI staff, Thomas Ehrgood, Compaq, Pierre Adornato, Nortel Networks; Steve Whitesell, Advanced American Telephones; and Roberta Breden, TIA staff.

The meeting discussion addressed the status of the proposed NPRM on the deregulation/privatization of equipment registration and telephone network connection rules (47 C.F.R. Part 68) within the Commission, and any questions the Commission might still have regarding this issue. Covered in the discussions were:

- Definition of Supplier's Declaration of Conformity (SDoC);
- Privatizing the Part 68 Registration Information Database; and
- Examining the combination of Part 15 and Part 68 customer premises equipment labeling.

Thank you.

Sincerely,

Roberta E. Breden  
Director, Technical and Regulatory Affairs

cc with attachments:  
Parties of Record

# **Ex Parte Presentation**

PART 68 of the FCC's Rules and  
Regulations;  
CC Docket No. 99-216

October 20, 2000

The Information Technology Industry Council  
The Telecommunications Industry Association

# **ITI/TIA Part 68 Ex Parte Meeting:**

## **Support FCC Part 68 Streamlining**

- Support FCC Proposal to Privatize Technical Standard Setting for Part 68
- Support Supplier's Declaration of Conformity (SDoC) for Equipment Approval
- Support Privatizing Registration Information Database
- Examine Combining Part 15 and 68 Labeling Requirements

# **Supplier's Declaration of Conformity: Equipment Approvals**

- International Industry Associations Agree on Advantages of SDoC without Mandatory Third Party Intervention
- Definitions of FCC DoC and International SDoC (ISO/IEC Guide 22) Differ
- SDoC is Based on Testing in lab of Supplier's Choice
- No Requirement to Use an Accredited Lab, Consistent With International Definition of SDoC

# **Supplier's Declaration of Conformity: Supported by Past Experience**

- Part 15 DoC and Verification Experiences Have Been Successful: No Significant Non-Compliance Reported
- European Union Accepts SDoC for Radio and Telecom Equipment (R&TTE Directive)
- SDoC Enhances U.S. Competitiveness For IT and Telecom Equipment

# **SDoC for Equipment Approvals: Telecom Certification Bodies**

- Telecommunication Certification Bodies (TCBs) Have Been in Existence Since June 2000
- SDoC Option would Allow Faster Time-to-Market Than Certification
- Manufacturers May Choose to Rely on Independent Labs for Services in Support of their SDoC

# Labeling

- Label Bears the Unique Product Identification
- Label Enables Access By Interested Parties to Sufficient Product Compliance Information
- Proposal Would Allow Combining Part 15 and Part 68 Labeling

# Registration Database

- Database Should Provide Sufficient Product Compliance Information for Carriers and Consumers to Contact Responsible Manufacturer
- FCC Should Transfer Part 68 Registration Information Database to the Private Sector
- Private Sector Will Investigate Creation of a Flexible, Scalable Service That Can Be Used For Additional Purposes Such as Recording Compliance With Non-U.S. Regulations

# Telecommunications Industry Association User Premises Equipment Division

## Proposal On

Database and labeling of CPE compliant with 47 CFR Part 68

Sept 26, 2000

### INTRODUCTION

In the FCC's 2000 Biennial Regulatory Review of Part 68 of the Commission's Rules and Regulations, CC Docket No. 99-216, the Commission proposed to combine the registration marks and equipment numbering systems for Part 15 and Part 68 equipment, discussed central database issues, and requested input on exact labeling format. In the Telecommunication Industry Association's ("TIA") comments on this NPRM, we indicated that TIA User Premises Equipment Division ("UPED") Committee TR41, Subcommittee TR41.11 was, "...working on this issue and that it will be producing an industry proposal that includes input from manufacturers, service providers, testing laboratories, and TCB's." This document represents the outcome of that work.

### OVERVIEW

After much consideration by a diversity of interested parties, TIA UPED recommends:

- the existing FCC Part 68 database<sup>1</sup> be transferred to and maintained by the designated gatekeeper organization;
- this same database be used for all future terminal equipment, until such time as a new enhanced database can be created;
- in order to reduce the labeling requirements we propose that a new terminal equipment identification format be adopted;
- all terminal equipment have a label that bears this unique identification.

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<sup>1</sup> In this document when we discuss the "database" we mean the computerized database that the FCC currently maintains. Those paper items required as part of the Form 730 application submission (primarily technical data and test results) should continue to be the responsibility of the FCC (or the TCB) who receives the submission package. In the event that Declaration of Conformity or Verification is adopted, this data should be maintained by the manufacturer and made available to the FCC upon request.

## **I. CENTRALIZED DATABASE**

It is clear that the FCC no longer intends to keep the database, data entry, and maintenance functions for equipment certified under 47 CFR Part 68. TIA UPED believes, however, that a centralized database is still essential for the following reasons, regardless of the approval process chosen by the FCC:

1. In the event that Customer Premises Equipment (CPE) caused harm to the Public Switched Telephone Network (PSTN), information required to initiate and control corrective action would be readily available.
2. A central database provides quick access to information needed by service providers to troubleshoot network harms issues.
3. A central database greatly simplifies product labeling. Except for information needed by consumers, the product label only has to provide a link back to the database.

TIA UPED proposes that initially the existing FCC database be turned over to the selected gatekeeper who would have the responsibility to update and maintain it without initially making any enhancements to it. UPED recommends that work should continue on the formulation of a new and improved database that contains a minimal but necessary set of product information.

Some information in the existing database maintained by the FCC under Part 68 is rarely accessed after the responsible party submits it. Since reducing the database results in a reduction of cost and time in building and maintaining it, TR41.11 is working with its members (which includes carriers, labs, and manufacturers) to determine which of the existing fields of the database would need to stay, which could be removed, and which may have to be added. This work is in progress and will be socialized with all interested parties when complete.

## **II. LABELING**

TIA UPED believes that it is necessary to maintain an identification number on products approved to Part 68 regardless of the approval level (Certification, Verification, or Declaration of Conformity) adopted by the FCC. This number would be the key identifier in case of a recall, and would serve as a pointer back to a central database that contains additional information about the product. We believe that the existing numbering scheme (refer to Appendix C) can be simplified (refer to Appendix D). Appendix A proposes a scheme that provides the minimum necessary amount of information in the product approval number. It also permits other labeling requirements to be relaxed (refer to Appendix D).

We also believe that it would be advantageous to combine the Part 68 and Part 15 numbering schemes. With the reduction in product size and the proliferation of marks required on products to satisfy various market requirements world wide any possibility to reduce the quantity of marks

required should be seriously considered. Appendix B provides a proposal for a numbering scheme that would permit the current Part 15 and Part 68 numbering requirements to be combined. Since the OET and the CCB currently issue grantee codes independently, it is possible that the OET Grantee code (“XXX” in Appendix B) and the CCB Grantee code (“AAA” in Appendix A) could be the same for two different applicants. If the FCC can coordinate the OET and CCB grantee codes, TIA UPED recommends adopting the combined approval number format.

Note that implementing the proposed Part 68 product number scheme does not require that the CCB and OET databases be combined. Our goal is a reduction in the product labeling requirements therefore this proposed numbering scheme provides that benefit and leaves open the option to combine the CCB and OET numbering or databases or both should that become achievable.

### **III. CONCLUSIONS**

TIA UPED has reviewed, through the work of the TIA TR41.11 sub-committee, the questions and concerns relating to database and equipment labeling which the Commission has outlined in its recent NPRM under Docket 99-216. In addition to its previously filed comments and reply comments, TIA UPED proposes the following conclusions that have been agreed to by all participating stakeholders and interested parties.

1. Some form of central database for terminal equipment approvals will be needed on an ongoing basis, regardless of approval method.
2. Task the selected gatekeeper with the responsibility of continuing the upkeep of the existing database of approved terminal equipment.
3. Industry, under the direction of the selected gatekeeper, will formulate plans on how to develop a new equipment approval database to take advantage of the Web tools and Web access that is now commonplace.
4. We propose a new numbering scheme to be used for all future terminal equipment approvals, regardless of approval method.

## **APPENDIX A - Proposed labeling/numbering scheme.**

With the exception of the letters “HAC” all the labeling information currently required for registration can be encoded into the registration number itself. The TIA UPED recommended format for this number is as follows:

Format: **FCC68: AAAEQYY123**

Where:

- FCC68:** Is a “fixed field” in the number that would serve to indicate that the CPE meets requirements of 47 CFR Part 68. The colon is an intentional separator between this fixed field and the number to eliminate confusion between these two parts.
- AAA** Is the existing CCB Grantee Code.
- EQ** Is an Equipment Code that would indicate to the Service Provider any special signal handling or billing requirements. Note that this could be different from the existing equipment codes listed in the Part 68 Application Guide. Any proposed changes will be addressed by TIA TR 41.11 in future revisions of the Part 68 Application Guide.
- YY** Is the REN without a decimal point (E.g. REN of 1.0 = 10, REN of 0.3 = 03). In the case of a “Z” ringer, ZZ would appear. In the case of registered components without a network interface “NA” would appear.
- 123** Is a product identifier, unique when combined with the responsible party’s Grantee Code, of at least one and up to 10 characters (including one or more dashes (-) if desired) similar to the product identifier used by the FCC OET in its FCC ID. This unique product identifier would be defined by the responsible party, not the FCC/TCB, and checked by the FCC/TCB for uniqueness within the applicant’s Grantee Code.

A sample label incorporating all the recommended information for Part 68 is shown below.

**FCC68: AAAEQYY123**  
**HAC**

## **APPENDIX B - Combining Part 15 and Part 68 numbers.**

TIA UPED believes that the OET's EMI and RF certification-numbering plan and the CCB's Part 68 certification number plan, could be combined using the certification-numbering proposal in Appendix A and the method described below:

The equipment numbering system used by the FCC's OET for Part 15 certification is given in 47 CFR 2.925 and 2.926 as follows:

Format: **FCC ID: XXX123**

Where:

XXX Is the existing OET Grantee Code.

123 Is the Equipment Code.

(The Equipment Code is a series of Arabic numerals, capital letters or a combination thereof that may include the dash or hyphen (-). The total of Arabic numerals, capital letters and dashes or hyphens shall not exceed 14)

The proposed Part 68 certification number is similar to the FCC ID defined in Part 2. If the 2-digit Equipment Code, 2-digit REN, and (up to) 10-digit product identifier are combined they can be considered an (up to) 14-digit Equipment Product Code, so that the following is possible:

Certification Code for Part 68 certified equipment: **FCC68: AAAEQYY123**

Certification Code for OET RF certified equipment: **FCC ID: XXX123**

Certification code for product with both certifications: **FCC68ID: AAAEQYY123**

Or: **FCC68ID: XXXEQYY123**

TIA UPED believes that the letters "ID" in the combined certification codes above is somewhat ambiguous and that using the letters "RF" would be less confusing.

NOTE: this proposal does not affect products that do not currently require an approval number on the label.

**APPENDIX C - Existing Part 68 labeling requirements.**

To better understand TIA UPED’s position on labeling of CPE, the existing labeling requirements given in 47 CFR Part 68 and the Part 68 Application Guide are shown in Table 1.

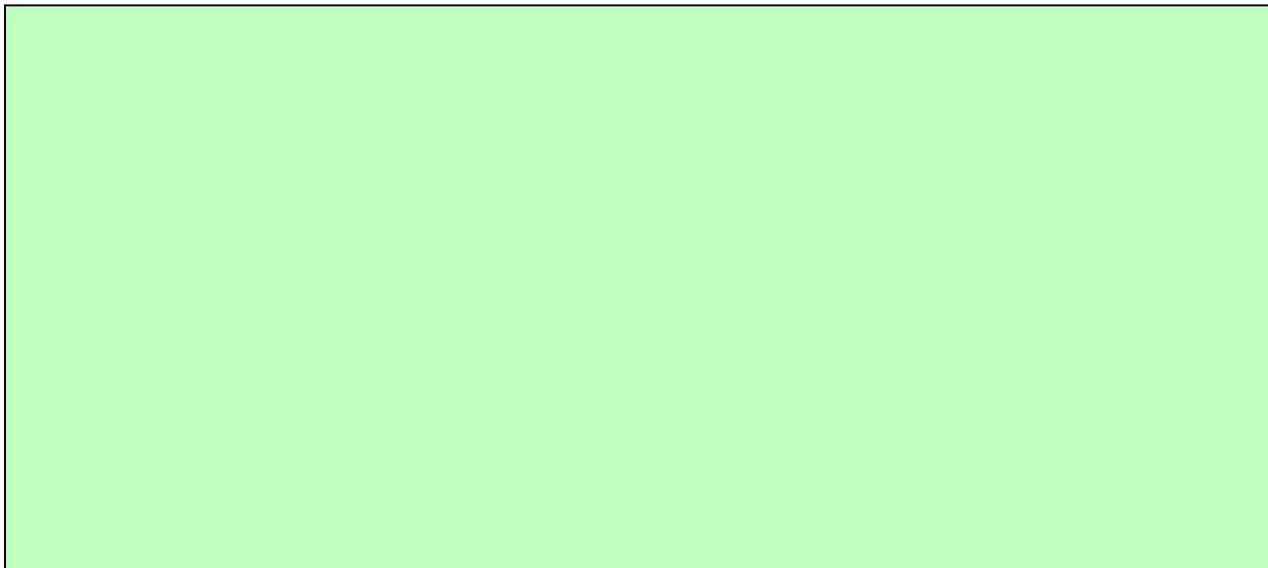
**Table 1: Existing 47CFR 68 Label requirements**

1	The statement “Complies With Part 68, FCC Rules” (Ref 47 CFR 68.300 (a))
2	FCC Registration Number (Ref 47 CFR 68.300 (a)) Format: AAACCC-XXXXX-EQ-S AAA = Grantee Code CCC = Country Code XXXXX = Number Assigned by the FCC EQ = Equipment Code S = Signaling Code
3	Ringer Equivalence Number (Ref 47 CFR 68.300 (a))
4	Grantee’s Name (Ref 47 CFR 68.300 (b))
5	Model Number (Ref 47 CFR 68.300 (b))
6	Serial Number or Date of Manufacture (Ref 47 CFR 68.300 (b))
7	Country of Origin (Ref 47 CFR 68.300 (b))
8	The type of phone jack used on the product (Ref. Part 68 Application Guide)
9	For telephones that meet the hearing aid compatibility requirements of §68.316 : (Ref 47 CFR 68.300 (c))  The letters “ <b>HAC</b> ”  (Note: For phones that do not meet § 68.316, there are marking requirements given in 47 CFR § 68.224 and 68.218.)
10	For Registered Components: (Ref. Part 68 Application Guide) A. The statement: “Component Registration Only (refer to instruction manual)”  B. For components without a network interface: ‘N/A’ on the label where the ringer equivalence would be stated.

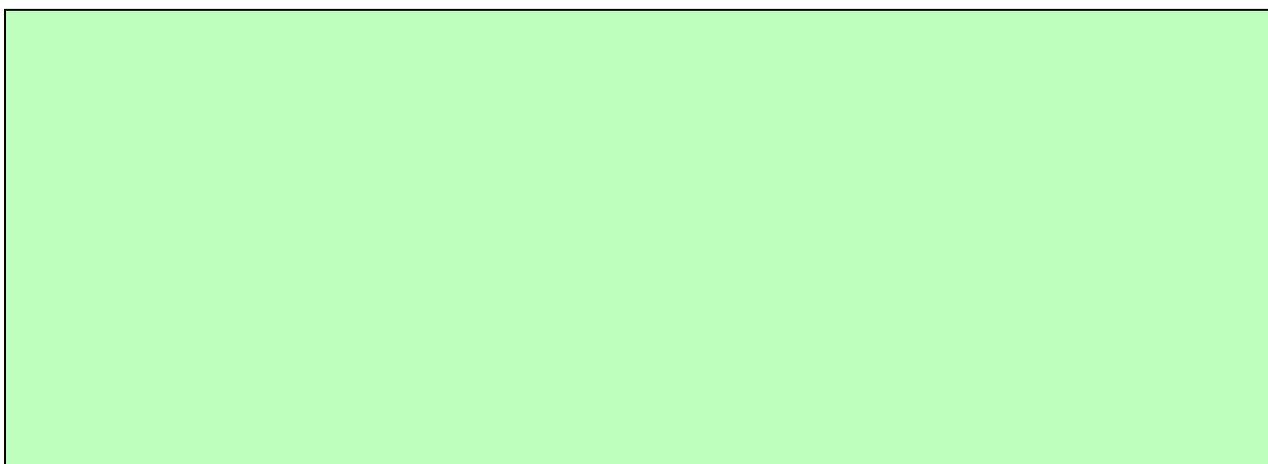
## APPENDIX D – Labeling Simplification

TIA UPED believes that labeling can be simplified as follows:

- A. The statement “Complies With Part 68, FCC Rules” can be simplified to “FCC68”. This still permits easy field determination that a product is compliant with Part 68 but minimizes the labeling required to do that. Further expansion of this idea is provided in Appendix B to include the OET requirements.
- B. Some of the information that is currently required by 47 CFR 68.300 is not needed on the product’s label. The information may be useful, but needn’t be on the product itself as long as it is included in a central database. The items that can be removed from Part 68 as a labeling requirement.:
  - i) The Plug / Jack designation
  - ii) The Signaling Code in the Registration Number.
- C. The Grantee’s name, required by 47 CFR 68.300, is already encoded in the Registration Number and need not be repeated on the product label. Therefore the Grantee’s name can be removed from Part 68 as a labeling requirement.
- D. The Model Number, although almost universally used on all products, should not be required on the label by Part 68 as a condition of attaining market access. It may help a responsible party in limiting a recall, but the actual recall would be based on the registration number, not the model number. Therefore the model number can be removed from Part 68 as a labeling requirement.
- E. The same logic applies to the “Serial Number or Date Code”. Although it can potentially be used to limit quantities in a recall and is almost universally used, it should not be required on the label as a condition of attaining market access. Therefore the serial number and date code can be removed from Part 68 as a labeling requirement.
- F. The country of origin requirement in 47 CFR 68.300 is a reminder that the product must be marked with the country of origin per Title 19, not an additional requirement beyond Title 19. Therefore the country of origin can be removed from Part 68 as a labeling requirement.
- G. The letters “HAC” used to indicate compliance with 68.316 are intended for use by HAC compatible hearing aid users and should be readable on the product. Therefore it should be retained as required marking on product compliant with 68.316. Additionally, products that do not meet HAC requirements should continue to be marked (on the retail carton and in the instruction book) per existing FCC rules 68.224 and 68.218.



**ICT Industry Green Paper on a  
Global Product  
Conformity Assessment System  
for the Future**



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## 1 Introduction

Industry organisations wish to make some comments from the Information and Communications Technology (ICT) sector on the issue of product conformity assessment for the future. The aim of this paper is to stimulate the debate on how the regulatory system should be adapted in the future to ensure that products can be placed on a Global marketplace with simplified and harmonised administrative procedures. This will benefit all parties - consumers, regulators and suppliers.

We use the term "simplification" in this paper to mean deregulation above a basic safety level, which to common understanding is necessary to protect the public interest. This short-term, achievable objective to remove unnecessarily complex regulations will significantly help to eliminate barriers to global trade.

We use the term "harmonization" in this paper to mean that common elements of product regulatory systems should be implemented in a manner, in whole or in part, by countries without unnecessary duplication or the imposition of conflicting requirements. "Harmonization" does not mean that the implementation of the common elements needs to be global, or shared, or identical from country-to-country, although they should be whenever practically possible. Harmonization is a longer-term objective that will further eliminate barriers to trade, but it should not be viewed as a pre-requisite for pursuing simplification measures or other improvements to product conformity assessment.

In the discussion of regulatory changes, it should be noted that the Mutual Recognition Agreements or Arrangements concluded so far do not by themselves require harmonisation of regulatory systems in different regions. They do however point out the differences that exist, and thus help the work for a global harmonisation. This paper does not question the need for regulation as such. This paper draws on some conclusions made in previous ECTEL<sup>1</sup> Position papers (for completeness one of them is included in this document as Appendix 1 and 2), and also some papers from other sources, notably the TABD<sup>2</sup> Declarations.

## 2 The Way Forward (Summary)

The regulatory system must be designed to meet basic needs of the society, leaving issues of performance and functionality of products for the market players to agree upon. Furthermore it is important that new innovative products can be placed on the market with maintained level of confidence and at lowest possible cost for administrative procedures. This leads to the need to simplify and harmonise regulatory procedures, and as a consequence there is also a strong need for deregulation.

Regulation and Market Surveillance should be such that there is little incentive for suppliers to place non-approved and/or non-compliant products on the market. This will benefit the serious manufacturers/suppliers and thus also the end-users of products.

It is proposed that

- a global conformity assessment system should be based on fair and simple rules;
- a global conformity assessment system should be suitable also for developing countries;
- horizontal regulation is applied wherever possible;
- the method used to show compliance to regulation is the Supplier's Declaration of Conformity (SDoC) without mandatory third party intervention;
- countries should deregulate as far as possible in a structured manner;
- the use of additional voluntary systems should only correspond to true market needs.

<sup>1</sup> The European Telecommunications and Professional Electronics Industry

<sup>2</sup> TransAtlantic Business Dialogue, see web page [www.tabd.com](http://www.tabd.com).

## 3 Discussion

### 3.1 General

Deregulation is starting to take place in many countries, specifically in the telecommunications field, to ensure a fast development of the society. Regulation will more and more concentrate on ensuring that certain public interest objectives are being met, and to ensure fair competition and a level playing field. In this scenario, consumer protection laws will play an increasing role, since quality and performance of products are no longer governed by strict regulation.

It is becoming increasingly clear that current product conformity assessment systems need to be evaluated for relevance in the new market scenario. Nowadays the commercial life cycle of ICT products is much shorter than before and thus it is crucial that the commercial window of opportunity is being utilised to the fullest. This has been addressed in the ECTEL Position Paper on Supplier's Declaration of Conformity (SDoC) and its accompanying paper on Accreditation (attached as Appendix 1 and Appendix 2).

The TransAtlantic Business Dialogue (TABD) has paid much attention to the matter of product conformity assessments and support the need for a simplified conformity assessment system for the global market where the supplier assumes full responsibility for the product.

The European Commission has issued papers on this subject. The position paper from DG III published in 1995<sup>3</sup> points out that "*there are two important aspects to the information revolution:*

- *The final shape information markets are going to take is unknown to regulators or economic operators.*
- *It is driven by innovation. Suppliers will have to respond to the demands of the market place and competitive interaction will determine which services are offered at what prices. There is general recognition that the main players will be private enterprises."*

In the DG III position paper it is also noted that "*the central issue to be addressed by regulators is, how to assure an appropriate balance between the many rights and competing interests affected by this revolution while keeping enough flexibility to facilitate and accelerate the realisation of the productivity gains and competitive advantages available from the information revolution and in particular from the extensive use of telecommunications equipment and services to support business and social needs."*

ECTEL's position papers are consistent with this position paper from DG III.

There are several issues that need to be considered when investigating the areas related to product conformity assessment. Among these is the global marketplace, which inevitably calls for more liberalisation and use of horizontal measures (where legal initiatives are deemed necessary). Some of these issues are discussed below.

### 3.2 A Global Marketplace

The marketplace for Information Technology and Telecommunications products is becoming truly global. This is perhaps best seen in the case of mobile satellite telecommunications (Low and Medium Earth Orbit satellites) where by necessity an identical technical solution is employed globally for each system.

A global marketplace inevitably calls for a simplified and harmonised conformity assessment regime. At present each region (and in some regions each country) has its own sectoral regulation for telecommunications. Although the systems are quite similar in many respects, there are still differences between them. Many of these differences are not directly related to technical matters, but rather to social issues (which however may translate into certain technical features or solutions that differ between regions).

A number of Mutual Recognition Agreements/Arrangements (MRAs) have been concluded, and new ones are being discussed. While it is of great advantage to have MRAs between certain trading parties, at least for the shorter term, it becomes difficult to manage a multitude of MRAs. The MRA between two parties

<sup>3</sup> DG III Industry (Legislation, Standardization and telematic networks): "Telecommunications Terminal Equipment regulatory framework - position paper" (Brussels, 15 June 1995)

needs updating as soon as the legal system in one country changes. On a global scale a longer term solution for simplified access to each other's markets should be contemplated.

The MRAs do not themselves require harmonisation of regulatory procedures<sup>4</sup>, or harmonisation of technical standards. As mentioned in Clause 1 they highlight the differences between the regulatory systems of the parties and thus point to areas where harmonisation could be beneficial. MRAs should be gradually revised towards a preferred global solution.

The best way to achieve global simplification and harmonisation is to deregulate or at least to minimise regulation. This is noted in the FCC Office of Plans and Policy's (OPP) Working Paper "Digital Tornado: The Internet and Telecommunications Policy"<sup>5</sup>. Where it is deemed necessary to apply legal measures, horizontal regulation should be applied wherever possible, thus leaving only certain sectoral aspects for sectoral regulation (see point 3.4). Global simplification and harmonisation of regulation is more easily achieved this way.

NOTE: In order to achieve technical harmonisation on a global level of the standards which support regulation the regulatory systems in the different regions should be equal, i.e. they should be targeting the same matters to the same level of confidence. As an example, at present the EMC standards (save the ones related to emission) created by IEC are written for voluntary, non-regulatory use. However in Europe these standards are being converted to European standards supporting the EMC Directive 89/336/EEC. There is a general concern that these standards exceed what is called for by the protection requirements in Article 4(b) of the EMC Directive, thus adding unnecessary costs to all products.

The success of a change in the regulatory systems is a question of timing. The window of opportunity has come for such a change in the different regions, to achieve a global marketplace thus reducing costs for bringing products on the market. This will in turn benefit the end-users.

There are ongoing discussions within the WTO framework on principles regarding conformity assessment and removal of technical barriers to trade. Industry proposes that a Conformity Assessment Agreement (CAA) in line with the principles outlined in this Green Paper be included in these discussions. See Annex A for a proposed CAA. This proposal addresses the IT sector, but following its successful implementation it may be found attractive to widen the scope of application to other sectors, so that the CAA would become horizontal.

It is recognised that basic horizontal legal systems related to aspects such as consumer protection and liability should be in place for a successful transition to a system based on SDoC and Market Surveillance. This is stressed in the UN Economic and Social Council input paper for the "Working Party on Technical Harmonization and Standardization Policies" meeting 18-20 May 1998<sup>6</sup>. See also clause 3.5.5 and Appendices 1 and 2.

<sup>4</sup> In some cases regulatory changes are needed in a country to allow for conformity assessment and approvals to be handled outside the country in question. This does not mean that regulation will be harmonised between the parties concerned.

<sup>5</sup> OPP Working Paper Series, 29 "Digital Tornado: The Internet and Telecommunications Policy", March 1997, page 47: "Government should think not only about the regulatory treatment of new services, but about the implications of those new services for the regulatory treatment of existing services. If a competitive imbalance exists because a new technology is not subject to the same regulatory constraints as a competing older technology, the answer should be reduced regulation of the older technology. Of course, such deregulation should be dependent on the existence of sufficient competition to police the actions of incumbents. The ultimate objective, however, should be less regulation for all, rather than more regulation for some."

<sup>6</sup> TRADE/WP.6/1998/8 8 May 1998: UN Economic and Social Council: Working Party on Technical Harmonization and Standardization Policies 18-20 May 1998: "Problems experienced by economies in transition relating to conformity assessment procedures - Supplier's Declaration of Conformity: Adaptation of procedures in terms of constraints on suppliers".

### 3.3 Horizontal regulation

The convergence which is now taking place between different sectors, specifically between telecommunications, media and information technology as discussed in the EU Commission Green Paper on Convergence<sup>7</sup>, will make it increasingly difficult to make a regulatory separation of different sectors. Since convergence will benefit the users of products and services, authorities should support this development by adapting (and wherever possible reducing) its regulation in a timely manner. The best way of doing this is to resort to horizontal regulation, and more reliance on competition rules to ensure a level playing field.

NOTE: ECTEL has responded with detailed comments to the Commission Green Paper on Convergence<sup>8</sup>.

Also, products are becoming multifunctional, and consequently they may be subject to a number of (at present) sectoral directives. Meeting the legal requirements related to one sector may result in non-compliance with legal requirements of another sector. The best way to ensure that combined products can enjoy easy market access is to use horizontal legislation. Sectoral legislation should be avoided wherever possible.

A first list of examples of horizontal issues, seen from the EU perspective, is given below. With reference to the TABD recommendations, it is expected that the EU Commission will take appropriate actions with respect to some of these issues.

Issue	Comments
Safety, including electrical safety	Safety has traditionally been subject to horizontal regulation, with appropriate technical standards and guidelines defining the criteria for compliance.
Radio and EMC	Spectrum management issues and the co-existence of products in the electromagnetic environment are horizontal issues. Due to the intrinsic similarity between radio and EMC, these should be covered by one regulatory framework.
Liability	Consumer protection and liability for defective products is a horizontal issue. There is no rationale to assign different regulatory regimes for different technical sectors.
Privacy	Directive 95/46/EC on the processing of personal data provides a horizontal umbrella for privacy. This is enhanced by directive 97/66/EC on the processing of personal data and protection of privacy in the telecommunications sector. These directives fully cover protection of privacy.
People with special needs	Measures taken in sectoral directives are only targeted towards a limited number of sectoral products. Where legislation is deemed necessary, a high level of well-being and employment for people with disabilities is better achieved through horizontal measures <sup>9</sup> .
Environmental issues	Horizontal legislation (where legislation is needed) is preferred because of factors like: <ul style="list-style-type: none"> <li>- combined products</li> <li>- convergence between sectors</li> <li>- material content</li> </ul>

<sup>7</sup> COM(97)623, Brussels, 3 December 1997: "Green Paper on the Convergence of the Telecommunications, Media and Information Technology Sectors, and the Implications for Regulation - Towards an Information Society Approach".

<sup>8</sup> ECTEL Position Paper EPP06/98 (04/98).

<sup>9</sup> In the Treaty of Amsterdam (2 October 1997), Declaration 22 (Declaration regarding persons with a disability) states that "The Conference agrees that, in drawing up measures under Article 100a of the Treaty establishing the European Community, the institutions of the Community shall take account of the needs of persons with a disability". However it is strongly recommended to ensure horizontal application of Declaration 22 so that optimum solutions for persons with a disability can be found.

### **3.4 Sectoral regulation**

Sector specific regulation should be used only in special cases, and then related to specific sectoral aspects. It should only be applied for as long as it is needed. All aspects which can be treated on a horizontal basis should be covered by horizontal measures. The way to minimise sectoral regulation is to deregulate as far as possible. Where sector specific regulation is introduced, the administrative burden to manufacturers should be minimised. Specifically, the Conformity Assessment methods being used should as far as possible be the same as the one(s) used for horizontal regulation to enable one-stop shopping, thus minimising delays and costs (which ultimately will - at least to some extent - be passed on to the end-user). For a Global market, harmonisation of standards supporting regulation is much needed.

### **3.5 Ways to compliance**

One can envisage a number of different approaches to a future global system for product conformity assessment. The different approaches need to be scrutinised regarding their merits and drawbacks.

#### **3.5.1 No sectoral regulation at all**

A well functioning horizontal regulation could eliminate the need for sectoral regulation. Such horizontal regulation would ensure public interests and fair competition.

#### **3.5.2 National Type Approval**

Type approval is associated with costs and delays in product introduction. The delays are often considerable due to the fact that manufacturers need to assist the type approval body with equipment and expertise in the equipment to be tested, which means that type approval will have to be performed country by country rather than testing in all countries at once. This is particularly the case for SMEs, where there is a limited number of staff with expertise available for these tasks.

As a result small markets become unattractive for many suppliers. This will deprive users in these markets of innovative products. The consequences are obvious: large markets will function (longer) but small markets will only see illegal or very old products on their market.

#### **3.5.3 Global Type Approval**

A global type approval system needs co-operation between countries. All countries (democratic and non-democratic, developed and less developed) should be members with equal rights and obligations.

All countries have to create confidence-building authorities to allow for accreditation and notifications that are accepted globally. At a first glance a system like this could look attractive but in reality it will be too slow in supporting the fast development of innovative products. The cost will be enormous and only a few players will afford its implementation.

#### **3.5.4 Alternative approach - safe installation**

An alternative approach to "safety of products" as discussed in the subclauses above is the concept of safe installations (safety at workplace). This can be used at a local level, but can hardly be used for a global product conformity assessment. This is a kind of indirect product safety regulation that require a supporting local authority assessment system. Such a system cannot be expected to be found in many countries.

### 3.5.5 Supplier's Declaration of Conformity without mandatory third party involvement

A system based on the use of Supplier's Declaration of Conformity (SDoC) relies on the fact that National Authorities define the regulatory framework for safeguarding the public interests. The supplier can then decide how to show compliance to such regulation. However, this has to be done in such a way that all players have full confidence in the complete process. Failure in the introduction of the SDoC system will definitely stop these developments for a very long period. Therefore a well functioning Market Surveillance system is a prerequisite.

It is also desirable that a legal system that addresses consumer protection and liability is in place. Ideally these laws should be applied horizontally.

See Appendices 1 and 2 for a more detailed discussion on SDoC and alternative compliance mechanism than the mandatory use of accredited laboratories.

Considering all the pros and cons of the alternative solutions mentioned above it is strongly recommended to agree on the alternative with SDoC without mandatory third party intervention as the future system for showing compliance to regulation.

### 3.6 Placing on the market and right to use

"Placing on the market" and "Right to use" need to be discussed as two issues, not one. This applies specifically where the use of equipment is subject to (user) licensing.

The placing on the market ensures free circulation of goods, and a global marketplace for the sale of goods. The placing on the market should be based on the application of horizontal legal measures like EMC and safety of equipment.

Right to use may in some cases require a license or a contractual agreement between a user and an operator of a service (such as a telecommunications network). The right to use a particular piece of equipment may thus be restricted in certain countries/regions.

The concept of 'Right to Use' should, however, not result in different Network Operators placing different technical requirements on the Equipment.

### 3.7 Marking

As stressed by the TABD<sup>10</sup>, the use of one single mark indicating the presence of a SDoC where information about compliance issues are given, is strongly preferred. It needs to be stressed that marking of equipment (as required by regulation) is for administrative control purposes, and is not intended for the user.

### 3.8 Information to the user

In general, consumer protection laws ensure that users are not being misled regarding the product they are buying. Horizontal regulation inevitably calls for an increase in the information being given to the end-user regarding the intended use of a product. It is important that users are made aware of certain limitations in the use of a product where this is not obvious. Any limitation regarding installation (e.g. regarding its EMC performance) should also be indicated to the user. The documentation associated with the product will also provide information about performance issues and compliance to relevant standards.

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<sup>10</sup> Conformity Assessment and Product marking (CAPM) paper Rome 6-7 November 1997, Clause 7.2, Recommended Action 2: "Industry, customers and governments should jointly develop a strategy for reducing the number of national and regional product marks. The approach of ISO/CASCO to create a guide for the use of a single symbol indicating the existence of a Suppliers' Declaration of Conformity should be closely followed to ensure the creation of a global symbol that adds value to all users."

### 3.9 Market surveillance

Regardless of conformity assessment system used to show compliance to its regulation, a country has to maintain a market surveillance system due to two reasons:

- Illegal and unsafe products should not be allowed to be put on and remain on the market.
- Fair market conditions should prevail. Suppliers which follow the rules and bear the administrative costs and delays due to regulations should not be disadvantaged compared to those who do not comply with the rules.

Since market surveillance is needed in all cases regardless of whether there is a third party intervention or not in the conformity assessment process (note that there will always be those who do not follow the rules), there are no or very little extra costs associated with the use of "SDoC without any third party intervention". It is rather a question of making the results from market surveillance publicly available thus raising the awareness of suppliers and users.

Market forces when allowed to function properly ensure that users get the best value for money.

### 3.10 "Outsourcing Competence" to Test houses

As long as industry is made responsible for its products they will act in relation to the risks involved. In many situations it can be expected that industry will outsource competence by using the services of third parties to verify its products, e.g. to be as well positioned as possible if their products are being challenged. This approach is beneficial to the suppliers who may choose not to establish the expertise or facilities within their organisations. It might be beneficial from a quality point of view and/or for optimizing cost associated to the conformity assessment process as well.

### 3.11 Next steps

Different regions or countries are in different stages of liberalisation and deregulation. Consequently the steps that need to be taken to arrive at the goal (as outlined in Clause 2) will differ somewhat between regions or countries. In driving towards this goal simplification of existing procedures will assist the process of harmonisation.

It is proposed that a discussion is initiated, region by region, regarding how to best adapt the existing regulatory systems so that the future goal is reached in a structured manner within a reasonable time.

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## Annex A

### Proposal for a Conformity Assessment Agreement for regulatory requirements of the ICT Sector

#### A.1 Introduction

Following the completion of the WTO Information Technology Agreement (ITA) on the abolition of tariffs on Information Technology products, there now comes the time to look for further reduction of non-tariff barriers related to the trade in goods, specifically regarding Information and Communications Technology (ICT) products.

A number of non-tariff measures exist which should be addressed, as concluded by the TABD Berlin conference 29-30 October 1999, . Global agreement on the use of Supplier's Declaration of Conformity (SDoC) as the general means to show compliance to standards, be they regulatory or voluntary is requested. The TABD documents also call for the use of international (global) standards.

In the course of the negotiations of the MRAs between the US and EU it has become apparent that the regions are using similar but not fully identical regulatory systems and standards. The goal appears to be the same, namely to safeguard public interests.

The MRAs themselves do not address simplifications. They will however point to unnecessary costs for suppliers in bringing their products onto the market - costs that eventually will be passed on to the final user. International agreements like the WTO ITA process can be instrumental in bringing down such costs.

Clause A.2 below proposes a Conformity Assessment Agreement (CAA) for the EETIS sector<sup>11</sup> on the general use of SDoC. The CAA needs to include Market Surveillance, because this is a necessary complement to the SDoC.

Use of global standards is in most cases subject to the regional and national standardisation bodies accepting such standards for their own needs. The signatories of a "Conformity Assessment Agreement" should be able to influence their respective national standards bodies to adopt international standards wherever possible.

#### A.2 Definitions of the Conformity Assessment Agreement (CAA) for regulatory requirements

When making the investigation about the possibility of achieving a CAA for regulatory requirements, it is important that all parties involved are in agreement on the definitions of CAA, SDoC and Market Surveillance.

In Europe the Council Decision on a Global Approach to Testing and Certification (93/465/EEC) lists a number of ways - modules A to H - to show compliance to New Approach (Council Resolution 85/C136/EEC) directives<sup>12</sup>. In all of these cases the supplier must prepare a written Declaration of Conformity. This means that even for the case where there is a strong mandatory third party intervention, there will also be an SDoC.

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<sup>11</sup> Electrical, Electronic, Telecommunications, Information Technology Sectors (EETIS) paper Rome 6-7 November 1997, clause III "Trade Facilitation, Regulatory Reform, and Conformity Assessment".

<sup>12</sup> New Approach Directives are "technical harmonisation directives" where essential requirements are listed in "non-technical ways" and where the use of harmonised standards give presumption of compliance to the directives, although suppliers can use the text of the directive in question to show compliance).

One of the modules, module A, does not require any intervention by a third party. The supplier declares under his sole responsibility that the product meets all the essential requirements that apply to it, prepares the Declaration of Conformity and signs it, thus assuming responsibility for the compliance of the product with the given Directive.

In the New Approach Directives there is always an *a posteriori* Market Surveillance mechanism, complementing the *a priori* conformity assessment procedure.

In the TABD documents the expression "SDoC" has been used in a *de facto* way as meaning Module A of the Global Approach, i.e., no mandatory intervention by a third party. It is therefore proposed that the definition of the CAA includes this element. Definition of Market Surveillance is based on its use in EU Directives. Further guidance and definitions are given in IEC Guide 22.

**Supplier's Declaration of Conformity (SDoC):** Procedure by which a supplier gives written assurance that a product, process or service conforms to specified requirements. NOTE: The supplier is the party that supplies the product, process or service and may be the manufacturer, distributor, importer, assembler, service organisation etc.

**Market Surveillance:** Surveillance by a National Authority that products brought onto the marketplace and/or taken into service comply with relevant regulatory requirements. Where it is found that this is not the case, appropriate measures may be taken (such as withdrawal of the product from the market).

**Conformity Assessment Agreement (CAA):** An agreement on the use of the following conformity assessment procedure:

#### 1. The Supplier

- a) ensures by way of technical documentation (which may include design calculations, test reports, etc. as appropriate) that the product (or the relevant part thereof) complies with the requirements in one or more legal (or voluntary) measure that are applicable to it, such as a Directive or Rule;
- b) prepares a written Declaration of Conformity (SDoC);
- c) takes all measures necessary in order that the manufacturing process ensures compliance of the manufactured product with the technical documentation.

There is no mandatory involvement of a third party in these processes.

**2. The National Authority** operates a Market Surveillance mechanism.

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## Appendix 1

### ECTEL position on Supplier's Declaration of Conformity

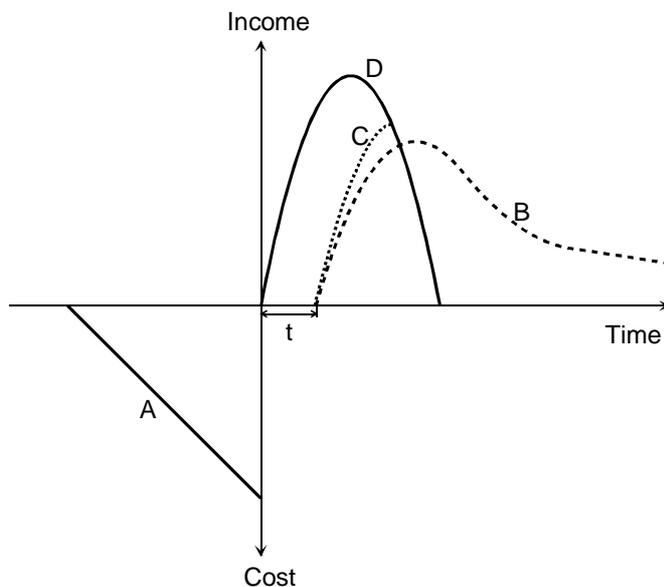
A conformity assessment system relying on Supplier's Declaration of Conformity (SDoC) is:

- fast;
- fair;
- flexible;
- safe.

#### Fast and Fair Time to Market

The emerging scenario with a Global Marketplace will lead to more competition, which benefits the customers. As a consequence, the time window during which a product is attractive for the market is becoming shorter and shorter due to more rapid and advanced product development. This time should not be spent waiting for formal approvals, since they do not add any value to the product. Rather, the time delay should be eliminated in order to maximise the potential revenue resulting from product development. In addition, eliminating the time delay for product approval would remove much of the incentive for the grey market (i.e. manufacturers who short-circuit the regulatory approval system).

The following figure illustrates this:



A: Accumulated development cost.

t: Time for type approval. The ideal solution is that this time is reduced to zero. The time is directly dependent upon the number of laboratories available.

B: "Traditional" income curve. Sales start after type approval, with quite extended after-launch sales.

C: Income curve after type approval in today's and tomorrow's business environment.

D: Possible income curve with shorter product life cycles and no delays in product approvals.

Every effort should therefore be put into allowing a product to be legally put on the market as soon as the supplier is prepared to assume legal responsibility for the product.

### **A flexible system**

The conformity assessment process should be an integral part of the development process. It is proposed that a three step approach, which takes into account the sensitivity/risk related to the product, be introduced:

- The preferred method is supplier's declaration without any third party involvement, and this should apply to all low-risk products (this method has been in operation in Europe for safety aspects of electrical products since 1973). Further discussion is given in document "Alternative Compliance Mechanism other than the Mandatory Use of accredited laboratories" (attached);
- The manufacturer operates a recognised quality system (e.g. ISO 9001), thus ensuring his competence in the field concerned;
- For high-risk products where there are health and hazardous risks, such as for pharmaceuticals and explosive goods, it might be desirable to have assessment by an accredited third party during the development phase. To make this system efficient, it is important to allow competition between the accredited bodies.

NOTE: In the second step above some manufacturers, particularly SMEs, might not wish to operate a quality system of their own but prefer an intervention by a third party.

This system, including an SDoC, can also be used for areas without regulation, e.g. for environmental issues, functionality and quality aspects.

### **A safe system relying on Market Surveillance**

To make the SDoC trustworthy, a market surveillance operation should be performed by the administrations.

Horizontal measures such as consumer protection and liability (related to safety of products) legislation are always applicable for the products concerned. The surveillance arising from the particular technical legislation should be proportional to the risks. Industry believes that the basis for such surveillance should be customer complaints. Industry also expects that the authorities establish a philosophy (based on proportionality) regarding market surveillance related to each sector.

Product documentation (which can be of a company sensitive nature) supporting the SDoC will be given to the surveillance authorities where there is a justified reason to believe that a product is not in conformity with the relevant regulatory requirements.

NOTE: Industry today uses more and more sub-assemblies from other companies. What information might be needed in a legal situation cannot be predicted at the time the product is brought onto the market. Documentation is stored in different formats in different companies from case to case.

**Conclusion**

The proposed system with SDoC will enable suppliers to quickly get a market presence, resulting in lower prices which benefit the users.

The grey market cannot be reduced by placing further regulations on those who have been proven to meet all relevant regulatory requirements. On the contrary, a simple regulatory system will reduce the commercial advantages that the grey market may have.

Regulatory authorities as well as test houses should only play the role of supporting users' and industry's needs in a safe, coherent and transparent environment.

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## Appendix 2

### Alternative Compliance Mechanism other than the Mandatory Use of Accredited Laboratories

#### 1 Introduction

Testing of a product is generally performed in order to gain information about its compliance with stated requirements. The manufacturer's product design specification includes requirements emanating from mandatory standards in different countries/regions as well as from customer requirements.

The regulatory requirements can be imposed either

- in the form of direct requirements in the applicable rules, or
- in the form of essential requirements in the applicable directives.. In this case suitable standards or specifications can be used to provide presumption of conformity with the directive.

Customer requirements are applied on a voluntary basis, however, from a business point of view meeting such requirements may be the difference between success and failure. The manufacturer therefore regards customer requirements as very important.

#### 2 Issues related to legislation

##### 2.1 The issue of confidence

A product shall be in conformance with all relevant regulatory rules and directives when placed on the market and used for its intended purpose. Authorities need a certain degree of confidence that this is the case for products on the market.

NOTE: The issue of confidence is also relevant in a supplier/customer relation; this, however, is in respect of performance aspects of the equipment.

Depending on the nature of the regulation, different measures can be taken to ensure that the confidence level is obtained. In order to reach the same confidence level one may have to use different measures due to the nature of the product (e.g. intervention by third party may be needed for the assessment of a high risk product, such as pharmaceuticals where there are health risks and explosive goods where hazardous situations may arise). Furthermore the measures can differ depending on the way the supplier has chosen to show compliance with the rule/directive. For example, in Europe proof of compliance with the EMC directive can be obtained either by application of relevant (identified) standards giving presumption of conformity with the essential requirements of the directive, or by examination of the product in direct relation to the essential requirements of the directive through the use of a "technical construction file". In the first case, the supplier does not involve any third party, but issues a Supplier's Declaration of Conformity (SDoC). In the second case a Competent Body is involved at certain stages, after which the supplier issues the SDoC. In both cases the supplier assumes full responsibility for the product.

## 2.2 The issue of proportionality

The principle of proportionality should apply in deciding the most appropriate measures. The measures put in place should be appropriate to the desired objective.

NOTE: In Europe, proportionality is the guiding principle for all legal measures, to ensure that measures are appropriate for their purposes, and that the measures do not go beyond what is necessary to achieve the objectives. This is stated in the Treaty of Rome, Article 3b, last paragraph: “Any action by the Community shall not go beyond what is necessary to achieve the objectives of this Treaty”.

When applying the proportionality principle it appears that the required level of confidence can be obtained through a simple SDoC for most rules and directives, without the need for mandatory third party involvement or accreditation of a manufacturer’s own laboratory. In all cases, the SDoC places the responsibility for a product firmly with the manufacturer/supplier. Apart from rules/directives related to technical aspects, product liability legislation is also applicable (but only related to safety).

For some products where there are health or hazard risks, such as pharmaceuticals and explosive goods, a tighter system of proof of conformity may be applied to achieve the desired level of confidence.

## 2.3 Market surveillance

A market surveillance operation should be performed to make the SDoC trustworthy.

Horizontal measures such as consumer protection and liability aspects are always applicable for the products concerned. The surveillance arising from the particular technical legislation should be proportional to the risks, i.e., different “levels of surveillance” should be used as appropriate. Product documentation (which can be of a company sensitive nature) supporting the SDoC will be given to the surveillance authorities where there is a justified reason to believe that a product is not in conformity with the relevant regulatory requirements.

NOTE: Industry today uses more and more sub-assemblies from other companies. What information might be needed in a legal situation cannot be predicted at the time the product is brought onto the market. Documentation is stored in different formats in different companies from case to case. It is in the interest of the industry to support administrations with the best information possible but only when there is a justified need.

## 3 Issues related to supplier/customer relation

In a supplier/customer relationship, compliance with voluntary standards is a matter of negotiation between the parties involved. In this case the issues of confidence and proportionality are also relevant. However, in these cases commercial aspects (price, delivery time, maintenance etc.) play an important role.

For commercial reasons, when dealing with particular customers, a manufacturer may involve a third party, or agree the accreditation of his testing facilities, or operate a quality system e.g. ISO 9000, as the case may be. In each of the cases the cost aspects affecting price and delivery would be for discussion with these customers.

## 4 When is there a need for accreditation of laboratory facilities?

### 4.1 Functions implemented through software

The behaviour of products, and specifically Information Technology and Telecommunications products, is largely dependent upon the software which controls the product. For the testing of software, special instruments are used to determine the compliance of a product with certain standards. It is the test instrument rather than the test engineer that will determine whether the product passes or fails the test. Therefore, as long as the manufacturer uses validated test instruments for his tests, no added value is gained by using a similar instrument at a third party (accredited) laboratory.

It is the manufacturer who has the knowledge about the behaviour of the product, and it is he who prepares the product for testing. This includes the setting of software parameters, provision of suitable external stimuli etc. The manufacturer assumes responsibility for the proper setting of such parameters. Thus it is the manufacturer rather than the test house engineer that will determine whether the product is correctly stimulated and operated during the test.

In practice there is no increase in the confidence level by accreditation of testing facilities when verifying functions implemented through software. The SDoC provides for the necessary responsibilities involved.

One should also note the fact that nowadays the user can control many functions by using his own software which runs on top of the original software. Sometimes the user can control the lower layer functions by parameter settings (e.g., X.25) without any identified problems.

### 4.2 Functions implemented through hardware

The proper functioning of hardware is nowadays checked with intelligent test equipment, especially in the case of new technologies such as ISDN and digital mobile telephony. The product to be tested is simply connected to the test instrument in a manner agreed by the manufacturer and the test engineer. This is similar to the discussion in point 4.1, and results in the same conclusion.

For horizontal rules/directives such as EMC and safety, compliance standards and guidelines are quite often general to cover a broad range of products. The manufacturer has the detailed knowledge about the product which is needed to enable it to be assessed against the requirements. He may use internal technical expertise to perform the required product inspections and testing, or he may buy such expertise externally as discussed in point 5.

Therefore, for most products the desired confidence level is obtained by using a simple SDoC. This procedure should apply to all products save for high-risk products where there are health or hazardous risks.

**NOTE:** In Europe, this method has been in operation for safety aspects of electrical products since 1973, and for EMC aspects of non-radio transmitting products since 1989.

For some products, it is still necessary to require that the manufacturer operates a recognised quality system (normally ISO 9000), or to require him to use an accredited testing facility. The trend now is to move towards SDoC.

For high-risk products where there are health or hazardous risks (such as pharmaceuticals and explosive goods) there is often a rationale for the involvement of an accredited third party for the assessment function in order to achieve the desired level of confidence.

## 5 Use of independent (accredited) laboratories in the voluntary field

The testing laboratories will probably see a change in the services requested by their customers (manufacturers and suppliers). Due to simplifications and harmonisation of legislative procedures regionally and globally, there will be a decline in the requests for "regulatory" testing. However, certain areas (e.g., EMC and safety) require a very detailed technical knowledge, so much so that a manufacturer may find it more profitable to buy this knowledge from external experts. The experts may perform inspections of the products as well as some tests.

An independent laboratory with proven competence can sell its services to a manufacturer in various phases of a product's development cycle:

- as a competence centre during the development phase;
- as a verification centre for the final product check.

A manufacturer may wish that an independent laboratory is accredited for its task in order to give the manufacturer enough confidence of the skill of its personnel and its ability to separate "design support" activities from "final verification" activities. The manufacturer is still fully responsible to his customer for the activities related to testing and verification of the product.

## 6 Conclusions

Accreditation of laboratories is not the only solution for obtaining the desired confidence that products are in conformity with relevant rules/directives. In the spirit of proportionality it is time to place the responsibility for their products firmly on the manufacturers by use of a Supplier's Declaration of Conformity regime. Where needed, this is complemented by a surveillance performed by the authorities.

The increasing demand by customers that manufacturers operate quality assurance systems will ensure that manufacturers use skilled personnel and appropriate test facilities when performing tests.

Regarding high-risk products where there are health and hazardous risks (such as pharmaceuticals and explosive goods) there is probably a need for the involvement of an accredited third party for the assessment function.

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