

*Eurolab workshop  
Accreditation  
with flexible scope  
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*Needs of notified bodies for "New Approach"  
Directives*

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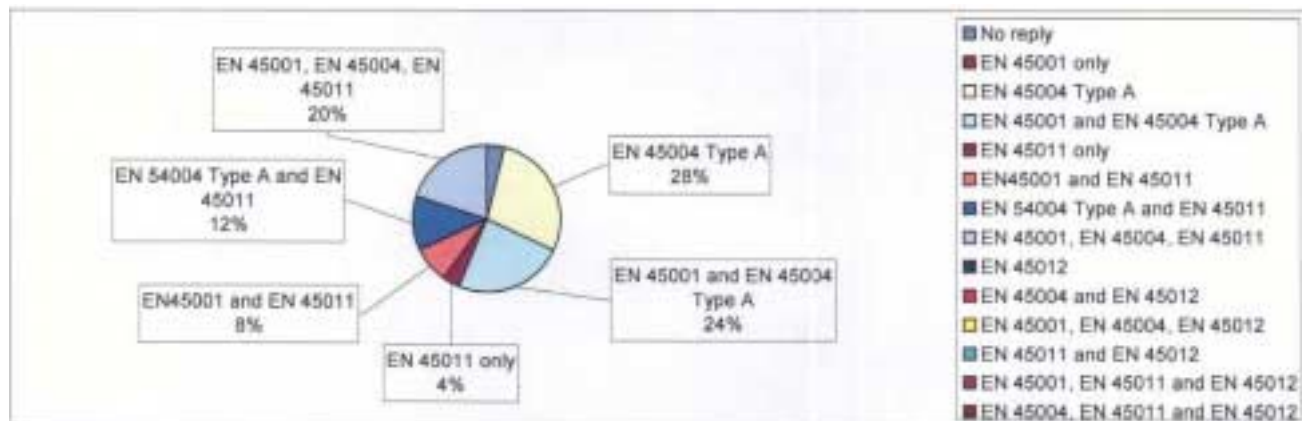
# What will be the menu today ? ?

1. Some aspects of today's situation
  - Impact of the applicable standard
  - Some existing practices in the definition of the scope
2. The possible ways forward
  - Basic principles
  - Practical consequences

# 1. Some aspects of Today's situation

## Impact of the applicable standard (1)

- Since there is no perfect match between the EN ISO 17000 series and the modules, a lot of combinations have been found adequate by the national authorities and/or the accreditation bodies. The nature of the standard will often have an effect on the formulation of the scope. A first illustration of the taken options can be given by an enquiry organised by the Commission (possibilities for module B)



Results of the survey conducted by the PED ADCO\* group on how Member States notify and monitor Conformity Assessment Bodies

# 1. Some aspects of Today's situation

## Impact of the applicable standard (2)

Similar situation for the Module B of the Machinery Directive (Results of the enquiry of the European Coordination “machinery” – 2006 – 46 notified bodies from 15 countries). The applicable standards are

- EN 45011+17020+17025 : A, FIN, SP
- EN 45011+17025 : D, SL
- EN45011+17020 : I (1)
- EN 17020 : B, F, UK
- EN 17020+17025 : UK
- EN 45011 : I (1), CH
- EN 45012: I(1)
- Principles of the 17000 series standards : I, LI, PL
- ISO 9001 (part of the requirements) : SK, PL (1)

# 1. Some aspects of Today's situation

Some existing practices in the definition of the scope

## DISCLAIMER

- This exercise is based on information publicly available on internet.
- The exercise was an opportunity to discover that very few explicit references to European Directives are made in the databases of the European Accreditation bodies. It is thus almost impossible to make a somewhat exhaustive study.
- The examples provided are for practical illustration only. The purpose is to initiate a discussion based on facts instead of general principles and or feelings.

# 1. Some aspects of Today's situation

## Some existing practices in the definition of the scope

### First example : the Low Voltage Directive (2006/95/EC)

- The activities of notified bodies are very specific. Article 8.2 reads “In the event of a challenge, the manufacturer or importer may submit a report, drawn up by a body, which is notified in accordance with Article 11, first paragraph, point (b), on the conformity of the electrical equipment with the provisions of Article 2”. The notified body may also be requested to provide an opinion to the Commission according to Article 9. Basically it goes about **testing activities** according to harmonised standards. The issue is that there are hundreds of standards changing frequently.

# 1. Some aspects of Today's situation

## Some existing practices in the definition of the scope (LVD)

Example 1 : A laboratory with a very detailed scope of accreditation (76 pages covering ATEX EMC and LVD). It is supposed that this was the base for notification.

| Materials/Products tested   | Type of tests/Properties measured/Range of measurement    | Standard specifications/ Equipment/Techniques used   | Location Code |
|---|---|--|---------------|
| SECTION 9: HOUSEHOLD AND SIMILAR ELECTRICAL APPLIANCES<br><br>Mains operated electronic and related apparatus for household and similar general use<br>Including:<br>Audio<br>Radio<br>TV<br>Video<br>and ancillary apparatus | <u>Electrical Products Tests</u><br><br>Electrical safety | BS EN 60065:2002<br>EN 60065:2002<br>IEC 60065:2001<br>Excluding:<br>Clause 3.1, Sound pressure test<br>Clause 8.17, Insulated winding wires<br>Clause 8.18, Wound components<br>BS EN 60065/BS 415:1994, Amd 1<br>EN 60065:1993, Corrig<br>IEC 60065:1985, Amds 1 to 3<br>BS 415:1990<br>HD 195 55<br>Excluding:<br>Clause 15 Mechanical strength of picture tubes and for protection against effects of implosion<br>BS EN 60065/BS 415:1995, Amd 1<br>EN 60065:1996<br>IEC 60065:1998<br>Excluding:<br>Clause 15 Mechanical strength of picture tubes and for protection against effects of implosion | CR            |

# 1. Some aspects of Today's situation

## Some existing practices in the definition of the scope (LVD)

Example 2 : A laboratory with a selected scope of accreditation (6 pages). The basic idea is that if the laboratory is able to demonstrate its capacity for the most difficult/representative test, it can be assumed to be competent for the other ones.

| Subject  | Internal ref.    | Range          | Reference standard   | Inspection method (*) |
|--|------------------|----------------|--|-----------------------|
| Household appliances   | PRC AVI/3P-M720F | Not Applicable | EN 60335-1 "Safety of household and similar electrical appliances" - Safety Part 1 General requirements<br>Except : § 15.1, § 22.32 alinea 3, § 30.3, § 32         | 1                     |
| Household appliances<br>Vacuum cleaners<br>Water suction cleaning appliances | PRC AVI/3P-M720F | Not Applicable | EN 60335-2-2 "Safety of household and similar electrical appliances"<br>Part 2 : Particular requirements for vacuum cleaners and water suction cleaning appliances | 1                     |
| Household appliances<br>Electric irons                                       | PRC AVI/3P-M720F | Not Applicable | EN 60335-2-3 "Safety of household and similar electrical appliances".<br>Part 2 : Particular requirements for electric irons                                       | 1                     |

# 1. Some aspects of Today's situation

## Some existing practices in the definition of the scope (LVD)

Example 3: A product certification body with a very generic scope

| Product <sup>1</sup> / Product Group | Certificatie Scheme   | Standard / Normative Document                                  |
|--------------------------------------|---|--|
| Electrical and electronic equipment  | EMC (Electromagnetic Compatibility) directive <ul style="list-style-type: none"> <li>▪ Review of technical documentation (annex III, subclause 3)</li> <li>▪ Review of technical documentation (art. 10.2)</li> </ul> | European directive 2004/108/EC<br>European directive 89/336/EC |
| Electrical equipment                 | LVD (Low Voltage) directive <ul style="list-style-type: none"> <li>▪ Review of technical documentation (art. 8.2 en 9.3)</li> </ul>   | European directive 73/23/EC                                    |

# 1. Some aspects of Today's situation

## Some existing practices in the definition of the scope

### Second example : the directive 2006/42/EC (Machinery).

- Historically, the machinery directive had only one module (type examination – module B). There were two very specific modules (check of correct application of the standards or filing) which will disappear in the new directive. Technically, the assessment is very often based on **engineering judgement** and the activity can be considered as **inspection**. It is also reasonable to consider it is related to product certification. For some very specific products, ROPS, FOPS.... the activity is pure testing (with, in addition, the intellectual capacity to fill a certificate).

# 1. Some aspects of Today's situation

## Some existing practices in the definition of the scope (Machinery)

Example 4: An inspection body with direct reference to the category of product identified in the Annex IV.

| N°2 : ÉLECTROMÉCANIQUE  |  |
|---|--|
| Phase, type et objet des inspections  | Référentiels d'inspection<br><i>(réglementaires, normatifs, CdC, ...)</i>  |
| <b>2.1 – Equipements de travail</b>   |  |
| <b>2.1.1 – Prestations d'organismes habilités pour les machines et les composants de sécurité</b> <ul style="list-style-type: none"> <li>➤ Examen CE de type au titre de l'annexe IV de la directive machines               <ul style="list-style-type: none"> <li>○ Examen CE de Type d'Appareils de levage de personnes avec un risque de chute verticale supérieure à 3 m</li> </ul> </li> </ul> | Directive Machines 98/37/CE transposée en droit français par les décrets 92-765 à 92-767 du 29 juillet 1992 et 96-725 du 14 août 1996 codifiés et leurs arrêtés d'application<br><br>Code du travail notamment article R233-86<br><br>Fiches des coordinations françaises et européennes des organismes notifiés |

# 1. Some aspects of Today's situation

## Some existing practices in the definition of the scope (Machinery)

Example 5: A product certification body with direct reference to 93 harmonised standards. This certificate is still valid and was issued in 2005.

### Safety of machinery:

| No | Standard    | Year | Title  |
|----|-------------|------|--|
| 1. | EN 292-1    | 1991 | Safety of machinery - Basic concepts, general principles for design - Part 1: Basic terminology, methodology.          |
| 2  | EN 292-2    | 1991 | Safety of machinery - Basic concepts, general principles for design - Part 2: Technical principles and specifications. |
| 3  | EN 292-2/A1 | 1995 | Safety of machinery - Basic concepts, general principles for design - Part 2: Technical principles – Amendment A1.     |
| 4  | EN 294      | 1992 | Safety of machinery - Safety distance to prevent danger zones being reached by the upper limbs.                        |
| 5  | EN 349      | 1993 | Safety of machinery - Minimum gaps to avoid crushing of parts of the human body.                                       |

## 2. The Possible ways forward

### Basic principles

- A. The relation between the scope of accreditation and the scope of notification should be unambiguous. The notifying authorities should not have to guess which modules and which products are covered by the accreditation.
- B. The direct reference to harmonised product standards in the accreditation scope may be possible for some directives (there are only 9 harmonised standards for the toys directive) but is highly hypothetical when it goes about directives supported by 1, 2 or 3 hundred standards.
- C. The identification of categories of products covered is sometimes possible and useful (Construction products, machinery, PPE....) sometimes irrelevant (PED...)
- D. Since none of the accreditation standards is perfectly fit for any module, several combinations are possible for the same purpose. The important issue is principle A.

## **2. The Possible ways forward**

### **Practical consequences**

### **Content of the scope of accreditation (NoBos)**

- A Reference to the European (and possibly national) regulatory acts**
- B. Reference to the applicable modules. Depending on the policy of the accreditation bodies/notifying authorities, several accreditation standards may be needed to support an accreditation on a wide range of modules.**
- c. Reference (when applicable) to the categories of product covered. Use of the wording of the directive to define the category.**
- D. Reference to harmonised standards if and when it brings added value.**

# CONCLUSIONS

- The proposed model is more based on a generic scope than on a flexible scope
- The issue is a strong challenge for the accreditation bodies, for the national authorities and for EA
- Have no fear of perfection – you'll never reach it (Salvadore Dali)

Thank you