

## JBCE comments/suggestions to the draft of blue guide (version 30 September 2013)

p. 41 and 45 – Instructions and safety information**Comment 1:**

As one of the obligations it is stated that the language in instruction and safety information should be easily understood by consumers and other end-users, as determined by the Member State concerned. For equipment intended for professional use, however, this requirement is not always the best solution. For example, the terminology applied in the instructions is related to the science behind, many users in international research centers require English only instead of the national language, and experts using the equipment come often from other countries than the country where the product is used.

**Suggestion 1:**

The sentence similar to the national authority (p. 42, the last paragraph) can be used for the professional users:

“The professional users often require instructions in a language which is different from the language(s) determined by the Member State concerned. Therefore in case the intended end-user is a professional or skilled person it is generally acceptable to provide instructions in English language or in a language agreed by means of a contract.”

**Comment 2:**

It is unclear whether in case of bundling many identical products in one package (e.g. installation equipment) each single product needs an instruction or whether it is sufficient to provide one instruction per packaging.

**Suggestion 2:**

on page 41, item 4. or the term “product” should be followed by an additional footnote saying: “In case where several identical products are bundled in a packaging for use in one application (e.g. installation equipment) it is sufficient to accompany the shipping unit with one set of instructions.”

p. 72 – Indication of the address**Comment:**

Here the Blue Guide seems not to be in line with NLF and the revised Directives. NLF requires that the manufacturer address must be indicated in any case independently from the location of the manufacturer (within or outside EEA). Blue Guide now mentions that the manufacturer contact address can be the address of the authorised representative. This means an EEA address instead of a non-EEA address can be indicated. In addition to that a European importer address must be also indicated. This would result in two European addresses which is in contradiction to the single point of contact requirement.

**Suggestion:**

The manufacturer address must be indicated. If the manufacturer locates outside of EU, additionally one contact address in EU must be indicated.

p. 84 - Affixing CE marking together with the identification number of the notified body

**Comment:**

For the cases where CE marking appears on products with an identification number, there is a possibility that a notified body does not intervene in the conformity process of some of directives/regulations to which the product is applied. For example, a notified body who intervenes in the design and production phase of a medical X-ray equipment does not assess the RoHS conformity.

**Suggestion:**

Add a note

Note: Even if CE marking appears with an identification numbers, there are cases where a notified body does not intervene in the conformity process of some of directives/regulations to which the product is applied.

p. 104 - Guidance for selecting the appropriate modules

**Comment:**

For the case where a product is subject to two or more directives/regulations, sometimes the module taken for conformity assessment for one directive/regulation is different from the module taken for that for other directives/regulations. For example, for the assessment for medical radiological equipment the module H is selected often under the MDD, while under the RoHS the module A is sufficient (In the RoHS directive this is clearly mentioned).

**Suggestion:**

Add one more point

- In the cases where two or more directives/regulations apply to a product, it is possible to select for each directive/regulation the most appropriate conformity assessment module.

Simple corrections:

p. 78 EN 17050-2 -> EN 17050-1

p. 87 See under 5.4.4 -> See under 4.5.2