CAPIEL
european coordinating committee of manufacturers of electrical switchgear and controlgear

New LVD / EMC / ATEX / RoHS Directives

Frequently Asked Questions

The provisions of the new LVD, EMC and ATEX Directives took effect on 20 April 2016, and the provisions of the new RoHS Directive took effect from 2 January 2013 (although most CAPIEL products will not have to comply with RoHS until later– see 6.2 below). Although many of the horizontal issues are already addressed in the European Commission's Blue Guide[1], some questions still remain, and this document sets out CAPIEL's understanding of the minimum recommended practices with regard to certain of these frequently asked questions (FAQ's).

The target audience is manufacturers of CAPIEL products, and it is assumed that the reader is already familiar with both the new directives and the Blue Guide (see Annex B).

This CAPIEL document is not intended to conflict with either the directives or the Blue Guide, and the reader should be aware that the relevant national transposition of each Directive is legally binding. If in doubt, the supplier of the equipment must seek his own advice on these issues and must not rely on this document alone.

CONTENTS

[1] "The 'Blue Guide' on the implementation of EU product rules 2016" (05 April 2016 version)

1. Introduction

This document addresses the new LVD, EMC, ATEX and RoHS Directives. These directives have been aligned with the New Legislative Framework (NLF). (See Annex B for links to these documents).

Although not specifically addressed in this document, the Radio Equipment Directive (2014/53/EU) is also aligned with the NLF and some parts of this document may therefore also be applicable to this directive.

2. Instructions and safety/EMC information

2.1. Content

2.1.1. General

Chapter 3.1 of the Blue Guide states:

> *"It is for the manufacturer to determine the relevant information which should be included in the instructions and safety information for a particular product."*

2.1.2. "Intended use"

Chapter 2.7 of the Blue Guide states:

> *"Intended use means either the use for which a product is intended in accordance with the information provided by the person placing it on the market, or the ordinary use as determined by the design and construction of the product."*

and

> *"Manufacturers are required to match a level of protection for the users of the products which corresponds to the use that the manufacturer prescribes for the product in the product information."*

The manufacturer should therefore specify the "intended use" of the product as this will help define the information that he needs to provide.

2.1.3. LVD

The "instructions and safety information" referred to in Article 6(7) shall address the essential requirements specified in Annex I.1(a) with regard to protecting against the hazards listed in points 2 and 3.

2.1.4. EMCD

The "instructions" referred to in Article 7(7) shall address essential requirements specified in Annex I.

The "Information concerning the use of apparatus" described in Article 18 shall also be included.

2.1.5. ATEX

The "instructions and safety information" referred to in Article 6(8) shall include the points specified in Annex II(1.0.6).

NOTE Some entries may not be applicable to CAPIEL products.

2.1.6. RoHS

The RoHS Directive does not specify any instructions or safety information.

2.2. Language

Most CAPIEL products (unlike consumer products such as a television, dishwasher, etc.) need to be professionally installed, integrated with other equipment from different manufacturers, and then configured in order to perform a specific function.

These products are typically sold via distribution chains to:

- Original Equipment Manufacturers (OEM's) for incorporation into machinery / equipment;
- Panel builders for incorporation into control panels;
- System Integrators (SI's) for incorporation into control systems / installations;

who may not be in the same country as either the manufacturer or the distributor.

Therefore, the CAPIEL manufacturer is often not aware of the location of the user, and therefore the language requirements. Furthermore, the directives do not specify which economic operator has to translate

the instructions and safety information. However, Chapter 3.1 of the Blue Guide does provide the following guidance:

> *"The manufacturer, importer and distributor have the obligation to ensure that the product is accompanied by instructions in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. It is for each economic operator which makes available the product in a Member State, to ensure that all the required languages are available."*[2]

For this reason, if it is necessary to provide instructions and safety information that is additional to that marked on the product, then CAPIEL recommends that the manufacturer should:

- Use symbols wherever possible (in order to avoid text) – see Annex A for some examples of commonly used symbols, *and*
- Provide either a paper copy or include the required information on the packaging in at least one EU language, *and*
- Provide the address of the manufacturer's free access web site (which includes other language versions) on the paper copy or packaging.

With regard to the second bullet above, Chapter 3.1 of the Blue Guide states:

> *"Unless otherwise specified in specific legislation, whilst the safety information needs to be provided on paper, it is not required that all the set of instructions is also provided on paper but they can also be on electronic or other data storage format. However, a paper version should always be available free of charge for the consumers who request it."*

2.3. Location hierarchy

Where possible, the instructions and safety/EMC information shall be marked on the product.

Where this is not possible, then the instructions and safety/EMC information shall be on the packaging and/or the accompanying documentation.

3. EU Declarations of Conformity (DoC's)

3.1. LVD, EMC and RoHS

Chapter 4.4 of the Blue Guide states:

> "*The single declaration of conformity can be made up of a dossier containing all relevant individual declarations of conformity*."

For market surveillance authorities (MSA's) the manufacturer can supply either:

- one single DoC covering all relevant CE marking directives, *or*
- a dossier (package) comprising all DoC's for that particular product. This dossier shall cover all relevant CE marking directives.

For customers:

- The manufacturer can supply either of the two options described above, or individual DoC(s), or nothing.

At the request of a MSA, the manufacturer shall provide the DoC in a language acceptable to the MSA.

To simplify translation of the DoC, CAPIEL recommends that manufacturers use the wording given in the Annexes of the directives – they can then perform a translation by replacing this wording with the equivalent wording from other language versions of the same directives.

[2] The national legislation that transposes each directive will specify the language requirements. The new Directives require that, before making a product available on the market, distributors shall verify that the product is accompanied by the required documents and by instructions and safety information in a language which can be easily understood by other end-users in the Member State in which the product is to be made available on the market.

3.2. ATEX

The manufacturer must ship a copy of the original DoC with the product. The ATEX Directive does not say that this copy of the DoC needs to be translated. This DoC can be either:

- one single DoC covering all relevant CE marking directives, *or*
- a dossier (package) comprising all DoC's for that particular product. This dossier shall cover all relevant CE marking directives.

At the request of a MSA, the manufacturer shall provide the DoC in a language acceptable to the MSA.

To simplify translation of the DoC, CAPIEL recommends that manufacturers use the wording given in the Annex of the directive – they can then perform a translation by replacing this wording with the equivalent wording from other language versions of the same directive.

4. Location of names and addresses

Chapter 4.2.2.1 of the Blue Guide states:

> *"The manufacturers must indicate the following three elements: their (1) name, (2) registered trade name or registered trade mark and (3) the address at which they can be contacted on the product, or, where that is not possible, on its packaging and / or in a document accompanying the product.*
>
> *The name and address must, as a rule, be affixed to the product. However, it may exceptionally be moved from the product if this rule cannot be followed. This would be justified where affixing it to the product was not possible under reasonable technical or economic conditions excluding however esthetical reasons. It is up to the manufacturer to make this assessment. This assessment has to be done according to the size or nature of the product. Some products e.g. hearing aids, sensors or the like are simply too small to carry such information*."

In cases where it is not possible to mark the information on the product itself, it is CAPIEL's understanding that the manufacturer can choose whether to put the information on the accompanying documentation **or** on the packaging.

CAPIEL encourages the use of a web address (in addition to the postal address mentioned above) in order to help direct queries to an appropriate contact.

NOTE The same requirements also apply for the importer details. In the event that the importer would have to open the packaging to put his name and address on the product, then he can instead put these details on the packaging and / or in a document accompanying the product.

5. Risk assessment

The new directives apply the following wording from Decision 768/2008:

> "*The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s)*."

Where possible, CAPIEL recommends that manufacturers use harmonised standards[3] that are listed in the Official Journal of the European Union (OJEU), whose date of cessation of presumption of conformity has not expired, and which therefore confer a presumption of conformity with the essential requirements to which they relate.

However, even when complying with such harmonised standards, it should also be noted that Chapter 4.1.1 of the Blue Guide states:

> *"Even where the manufacturer uses a harmonised standard (where its reference is published in the OJEU and which aims to cover certain risks) to satisfy essential requirements, the risk assessment has to be carried out and he must check whether the harmonised standard covers all risks of the product. This is because it cannot be assumed that the harmonised standard covers all requirements of all legislative acts applicable to a given product (or, indeed, all the requirements of the specific act under which it has been developed) or whether the product in question introduces also other risks not considered in the harmonised standard."*

[3] 'Harmonised standard' means a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation (*Regulation (EU) No 1025/2012*).

Chapter 4.1.2.2 of the Blue Guide explains the role of harmonised standards in this process and includes a diagram showing the generic philosophy for cases where a manufacturer needs to identify applicable essential requirements.

6. Implementation dates

6.1. LVD/EMC/ATEX

Products which are placed on the market from 20 April 2016 must comply with all aspects of the new LVD/EMC/ATEX Directives.

6.2. RoHS

The scope of the RoHS Directive will gradually extend to include more equipment categories and the two new categories of most relevance for CAPIEL products are:

Equipment Category	**Compliance Date**
Category 9 Industrial monitoring and control instruments (meaning "monitoring and control instruments designed for exclusively industrial or professional use")	22 July 2017
Category 11 Any other EEE that is not already covered by the other categories (i.e. a “catch-all”)	22 July 2019

Details of the restricted substances and associated exemptions are given in Annexes II, III and IV of the RoHS Directive.

Annex A

Examples of commonly used symbols

The following information is taken from the ISO Online Browsing Platform (OBP) at:
https://www.iso.org/obp/ui/#home

	**ISO 7010 (W012)** Title : Warning; Electricity Function/description : To warn of electricity Human behaviour that is intended to be caused after understanding the safety sign's meaning : Taking care to avoid coming into contact with electricity (See also IEC 60417-5036)
	**ISO 7010 (W017)** Title : Warning; Hot surface Function/description : To warn of a hot surface Human behaviour that is intended to be caused after understanding the safety sign's meaning : Taking care to avoid coming into contact with a hot surface (See also IEC 60417-5041)
	**ISO 7010 (M002)** Title : Refer to instruction manual/booklet Function/description : To signify that the instruction manual/booklet must be read Human behaviour that is intended to be caused after understanding the safety sign's meaning : Reading the instruction manual/booklet before starting work or before operating equipment or machinery
	**ISO 7010 (M005)** Title : Connect an earth terminal to the ground Function/description : To signify that an earth terminal must be connected Human behaviour that is intended to be caused after understanding the safety sign's meaning : Connecting an earth terminal of a product to the ground (See also IEC 60417-5017, 5018, and 5019 for specific types of earth connection)

Annex B

Links to Key Documents

Low Voltage Directive (2014/35/EU)
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0035&locale=en

EMC Directive (2014/30/EU)
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0030&locale=en

ATEX Directive (2014/34/EU)
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0034&locale=en

RoHS Directive (2011/65/EU)
http://ec.europa.eu/environment/waste/rohs_eee/legis_en.htm

European Commission: “The ‘Blue Guide’ on the implementation of EU product rules”
http://ec.europa.eu/DocsRoom/documents/4942/attachments/1/translations/en/renditions/native

Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008D0768&from=EN

Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R0765&from=EN