European Directives

An Overview for OEMs and System Integrators

Iain Lindsay

This document is an introductory guide to some of the requirements that apply to industrial automation equipment that is placed on the market or put into service in the European Economic Area. It does not constitute legal advice. The particular requirements that apply to a specific piece of equipment will require the supplier of the equipment to undertake a detailed and thorough analysis of all provisions that apply before then undertaking appropriate conformity assessment procedures in accordance with the legislation. The supplier of the equipment must seek his own advice on these issues and must not rely on this document alone.

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1. Introduction

In order to be placed on the market or put into service within the European Economic Area (EEA), industrial automation equipment must be in compliance with all applicable legislation. This legislation typically takes the form of a European Directive which is then incorporated into the laws and regulations of each Member State.

Further information on European Directives and their relationship with national legislation, European (EN) Standards, CE Marking, Declarations of Conformity, and other related matters is available in a publication titled "The ‘Blue Guide’ on the implementation of EU product rules" which is published by the European Commission and is available from the EU web site at: http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=7326&lang=en&title=%E2%80%98Blue%2DGuide%E2%80%99%2Don%2Dthe%2Dimplementation%2Dof%2DEU%2Dproduct%2Drules

2. Outline Methodology

The following is an outline methodology that may be of help when complying with some European Directives that involve CE marking:

i) Identify the applicable European Directives

Sections 3 and 4 of this document list the most common European Directives that apply to new industrial automation equipment. The actual directives that apply will depend on the exact nature and intended use of the equipment. Please note that other directives may also apply for certain types of equipment.

ii) Identify the applicable European (EN) Standards

Identify the current versions of the relevant EN Standards that contain detailed technical requirements which facilitate compliance with the essential requirements of the directives. The EU web sites listed in sections 3 and 4 of this document include links to the references of such EN Standards.

Section 8 of this document also includes links to the web sites of the three European Standards Organisations (CENELEC, CEN, and ETSI).

iii) Risk assessment and reduction

Identify, analyse and evaluate risks, reduce risks, take any necessary protective measures in relation to risks that cannot be eliminated, and inform users of residual risks (if any). The risk assessment should be based on a task analysis that takes account of all aspects of the life cycle and includes all types of foreseeable use including misuse.

iv) Identify the conformity assessment methods to be used

For each directive, select the appropriate design and production phase options. Depending on the type of equipment and the directive(s) involved, this could mean self-certification, 3rd party certification, or a combination of both.

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1 The Member States of the EEA are the 28 Member States of the European Union (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, The Netherlands, United Kingdom) plus Iceland, Liechtenstein, and Norway.

Similar legislation often applies in other European countries (e.g. Switzerland, Turkey).
v) **Design, build, and test the equipment in accordance with the applicable requirements**

See (i), (ii), (iii) and (iv) above.

Draw up the technical documentation (“Technical File”) containing information to demonstrate the conformity of the equipment to the applicable requirements of the directives. The use of components (products) which themselves comply with the relevant EN Standards (and are CE marked), and which are installed in accordance with the manufacturer’s instructions, does not itself ensure that the final equipment complies with any particular directive, but it does greatly aid and help simplify the subsequent conformity assessment of the final equipment. Conversely, the use of non-compliant components (products) can hinder, and even prevent, compliance of the final equipment.

vi) **Undertake any additional activities specified in the directive(s)**

e.g. instructions for installation, use, maintenance; product marking, etc.

vii) **Generate the Declaration of Conformity (DoC) and affix the CE Mark**

Certain European Directives (including the Machinery, LVD, EMC, ATEX, RED, Pressure Equipment, RoHS, and Ecodesign) require that equipment is CE marked and has a Declaration of Conformity:

- **CE marking**
  
The CE marking indicates the conformity of the product with the EU legislation applying to the product and providing for CE marking.
  
  By affixing the CE Marking the manufacturer declares on his sole responsibility that:
  
  - the product conforms to all applicable EU legislative requirements,
  
  - that the appropriate conformity assessment procedures have been successfully completed.

- **Declaration of Conformity (DoC)**
  
The Declaration of Conformity is the document that states that the product satisfies all the relevant requirements of the applicable legislation. By drawing up and signing the Declaration of Conformity, the manufacturer assumes responsibility for the compliance of the product.
  
The Declaration of Conformity must contain all relevant information to identify the product, the manufacturer, the authorised representative (where applicable), the EU harmonisation legislation according to which it is issued, the references of the harmonised European (EN) Standards or other technical specifications in relation to which conformity is declared, as well as any Notified Body certificates (where applicable), and any other information specified by the relevant directives.

These activities should be undertaken by the manufacturer, or his authorised representative established within the EEA.

viii) **Production control**

The manufacturer must take all measures necessary to ensure that the equipment is manufactured in accordance with the Technical File and with any provisions of the directive(s) that apply.

ix) **Retain the technical documentation**

Retain the technical documentation necessary to assess and justify the conformity of the equipment with the requirements of the directives for the duration specified.
3. Safety and EMC Directives

The European Directives that address safety and EMC issues and that are commonly applied to new industrial automation equipment are summarised below.

Where available, links are provided to official EU web sites that provide the text of the directive together with the official Guidelines, a list of the harmonised European Standards that confer a presumption of conformity with the essential requirements, and other relevant information.

3.1 Machinery Directive (2006/42/EC)

The Machinery Directive applies to the design, construction, placing on the market or putting into service of machinery. In particular, it specifies requirements relating to the design and manufacture of machinery in order to help improve its safety.

It applies to complete machines, assemblies of machines, partly completed machines, equipment intended for incorporation into machines, safety components, and certain other associated equipment. Under some circumstances, the manufacturer must involve a 3rd party known as a “Notified Body”. In other cases, the manufacturer can self-certify, or can voluntarily enlist the help of a Notified Body.


3.2 Low Voltage Directive (2014/35/EU)

The Low Voltage Directive (LVD) applies to electrical equipment designed for use with a voltage rating of between 50 and 1000 Vac and between 75 and 1500 Vdc.

The LVD covers all risks arising from the use of electrical equipment, including not just electrical safety aspects (e.g. electric shock, fire) but also mechanical, chemical, and all other risks. It also covers health aspects of noise and vibrations, and some ergonomic aspects.

In addition, electromagnetic aspects relating to safety including functional safety are covered by the LVD. This includes the effect of electromagnetic fields, emitted by electrical apparatus.


3.3 EMC Directive (2014/30/EU)

The EMC Directive regulates the compatibility of equipment regarding electromagnetic compatibility (EMC) which is defined as “the ability of equipment to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances to other equipment in that environment”.

The EMC Directive applies to a vast range of equipment encompassing electrical and electronic appliances, systems and installations. It is important that the manufacturer determines whether his equipment is considered “apparatus” or “fixed installations” as defined by the EMC Directive. Fixed installations are within the scope, but are treated differently to apparatus and do not need a CE mark or a Declaration of Conformity – similarly, there are also different rules for apparatus that is intended to be incorporated in a given fixed installation.

Most industrial automation equipment is installed in the “industrial” EMC environment.

3.4 ATEX Directive (2014/34/EU)

The objective of the ATEX ("ATmosphères EXplosibles") Directive (94/9/EC) is to help reduce the risks resulting from the use of certain equipment in, or in relation to, a potentially explosive atmosphere. It applies to both mechanical and electrical equipment capable of causing an explosion through their own potential sources of ignition, and protective systems intended to halt/limit incipient explosions. Many items of equipment require 3rd party certification from an ATEX Notified Body.

A second ATEX Directive (1999/92/EC) lays down “minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres” and also defines the various zones for gases, vapours and dusts.

- Ex certificates for Rockwell Automation products are available at: http://www.rockwellautomation.com/rockwellautomation/certification/ex.page?


The Radio Equipment Directive (RED) applies to electrical or electronic products which intentionally emit and/or receive radio waves for the purpose of radio communication and/or radiodetermination.

In addition to helping ensure the effective and efficient use of the radio spectrum, the RED is concerned with both safety and EMC, and incorporates many of the requirements contained within the LVD and EMC Directives.


3.6 Pressure Equipment Directive (2014/68/EU)

The Pressure Equipment Directive covers pressure equipment and assemblies with a maximum allowable pressure greater than 0.5 bar.

It covers a wide range of equipment such as vessels, pressurised storage containers, heat exchangers, steam generators, boilers, industrial piping, safety devices and pressure accessories.

Further information on the above and other pressure equipment directives is available at: http://ec.europa.eu/growth/sectors/pressure-gas/pressure-equipment
4. Environmental Product Directives

European Directives that address environmental aspects of equipment also need to be considered and are summarised below.

Where available, links are provided to official EU web sites that provide the text of the directive together with the official Guidelines, a list of the harmonised European Standards that confer a presumption of conformity with the essential requirements and other relevant information.

4.1 RoHS Directive (2011/65/EU)

The Restriction of Hazardous Substances (RoHS) Directive restricts the use of certain hazardous substances in electrical and electronic equipment.

The scope of the RoHS Directive includes “electrical and electronic tools”, but “large-scale stationary industrial tools” and “large-scale fixed installations” are excluded.

EU web site for the RoHS Directive:

4.2 WEEE Directive (2012/19/EU)

The Waste from Electrical and Electronic Equipment (WEEE) Directive addresses the collection, treatment, reuse/recycling/recovery, and environmentally sound disposal of WEEE.

The scope of the WEEE Directive includes “electrical and electronic tools”, but “large-scale stationary industrial tools” and “large-scale fixed installations” are excluded.

EU web site for the WEEE Directive:
http://ec.europa.eu/environment/waste/weee/index_en.htm

4.3 REACH Regulation (1907/2006)

Under REACH (Registration, Evaluation and Authorisation of Chemicals) the use or presence of certain substances may be restricted, may need to be registered with the European Chemicals Agency (ECHA), may need to be advised to the customer, may need to be notified to ECHA, or may need to be authorised by the European Commission.

REACH is very wide ranging and applies to an “article” (hardware) such as a complete machine, control panel, product, sub-assembly, component, etc. as well as to substances themselves.

NOTE REACH is a Regulation, not a Directive, meaning that it applies directly without the need for a national transposition.

EU web site for the REACH Regulation:
4.4 Ecodesign Directive (2009/125/EC)
The Ecodesign Directive creates a framework for the integration of environmental aspects in the
design and development of energy-related products. The eco-design requirements are detailed in
“Implementing Measures” which address specific products or product characteristics including
(but not limited to):

- Electric motors (3 phase induction motors, 0.75 kW to 375 kW)
- Fans driven by motors with an electric input power between 125 W and 500 kW
  (Commission Regulation (EU) No 327/2011)
- Power transformers with a minimum power rating of 1 kVA
  (Commission Regulation (EU) No 548/2014)

Ecodesign requirements are also under consideration for other equipment including variable
speed drives, pumps, compressors, uninterruptible power supplies (UPS), and machine tools.
EU web site for the Ecodesign Directive:

4.5 Batteries Directive (2006/66/EC)
The Batteries Directive applies to all types of batteries, regardless of their shape, volume, weight,
material composition or use.

The Batteries Directive addresses:
- the use of mercury and cadmium;
- marking requirements;
- removal of batteries at end of life;
- instructions and information for end-users;
- registration, reporting, and recycling.

EU web site for the Batteries Directive:
http://ec.europa.eu/environment/waste/batteries/index.htm

4.6 Packaging Directive (94/62/EC)
Its objective is to help reduce the overall impact of packaging on the environment, and it:

- restricts the use of lead, cadmium, mercury and hexavalent chromium;
- specifies “essential requirements” for the composition and the reusable and recoverable,
  including recyclable, nature of packaging;
- requires the recycling of packaging waste;
- specifies voluntary marking requirements.

EU web site for the Packaging and Packaging Waste Directive:
http://ec.europa.eu/environment/waste/packaging_index.htm

Safety directives (such as the Machinery Directive) apply at the point when the equipment is first made available for sale or use. The "employer" is then responsible for the safety of any work equipment (machine, apparatus, tool or installation used at work) throughout the life of the equipment.

The obligations of the employer are specified in the national regulations that implement the provisions of Directive 2009/104/EC "Minimum safety and health requirements for the use of work equipment by workers at work".


Directive 85/374/EEC concerning liability for defective products (the "Product Liability Directive") also applies to industrial automation equipment. It applies in addition to other more specific directives such as Machinery, LVD, EMC, etc.

Furthermore, it also applies to equipment that may be outside the scope of these other directives. In such cases, the requirements of the Machinery, LVD and other similar directives (together with their relevant standards) are a good starting point for ensuring that the requirements of the Product Liability Directive are satisfied.

7. Conformity of Rockwell Automation Products

The use of Rockwell Automation products which themselves comply with relevant European requirements (and are CE marked) does not itself ensure that the final equipment complies, but it does greatly aid and help simplify the subsequent conformity assessment of the final equipment.


These Declarations of Conformity can be downloaded in pdf format, and may be used as part of the technical documentation (see section 2(v) of this document) needed to support compliance of the final equipment.

8. Useful Links


CENELEC (European Committee for Electrotechnical Standardization) http://www.cenelec.eu

CEN (European Committee for Standardization) http://www.cen.eu

ETSI (European Telecommunications Standards Institute) www.etsi.org
9. Resources

Please contact the following companies for more information.

**Rockwell Automation**
Iain Lindsay
EU Regulatory Affairs
Tel +44 (0)1908 839548
email ilindsay@ra.rockwell.com
Web www.rockwellautomation.com