European Directives

An Overview for OEM's and System Integrators

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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)[1], 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 "Guide to the implementation of directives based on the New Approach and the Global Approach" (commonly referred to as the "Blue Book") which is published by the European Commission and is available from the EU web site at:
http://ec.europa.eu/enterprise/newapproach/legislation/guide/index.htm

2. Outline Methodology

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

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 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.

[1] The Member States of the EEA are the 27 Member States of the European Union (Austria, Belgium, Bulgaria, 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 also applies in several other European countries (e.g. Switzerland, Turkey).

v) ***Design, build, and test the equipment in accordance with the applicable directives and standards***
See (i), (ii), (iii) and (iv) above.
Construct a Technical File containing the technical documentation necessary to assess and justify the conformity of the equipment with the requirements of the applicable directives and standards.
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. Furthermore, the use of non-compliant components (products) can hinder, and even prevent, compliance of the equipment itself.

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, R&TTE, Pressure Equipment, and Ecodesign Directive) require that equipment is CE marked and has a Declaration of Conformity:

- CE marking
  The CE marking symbolises the conformity of the equipment with the applicable requirements imposed on the manufacturer. The CE marking affixed to equipment is a declaration by the person responsible that:
  - the equipment conforms to all applicable provisions,
    and
  - the appropriate conformity assessment procedures have been completed.
- Declaration of Conformity (DoC)
  The Declaration of Conformity should contain all relevant information to identify the directives according to which it is issued, as well as the manufacturer, the authorised representative (where applicable),the Notified Body (where applicable), the equipment to which it relates, references to harmonised European (EN) Standards or other normative documents, 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 harmonized 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.

- Safety certificates for various Rockwell Automation products are available at: http://www.rockwellautomation.com/products/certification/safety/index.html
- EU web site for the Machinery Directive: http://ec.europa.eu/enterprise/mechan_equipment/machinery/index.htm

3.2 Low Voltage Directive (2006/95/EC)

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 any other such 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.

- EU web site for the LVD: http://ec.europa.eu/enterprise/electr_equipment/lv/index.htm

3.3 EMC Directive (2004/108/EC)

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.

- EU web site for the EMC Directive: http://ec.europa.eu/enterprise/electr_equipment/emc/index.htm

3.4 ATEX Directive (94/9/EC)

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) on "minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres" defines the various zones for gases, vapours and dusts.

- Ex certificates for various Rockwell Automation products are available at: http://www.rockwellautomation.com/products/certification/ex/excert.html
- EU web site for the ATEX Directive: http://ec.europa.eu/enterprise/sectors/mechanical/atex/index_en.htm

3.5 R&TTE Directive (1999/5/EC)

The R&TTE (Radio equipment and Telecommunications Terminal Equipment) Directive applies to radio equipment and to telecommunications terminal equipment that can be connected to public telecommunication networks.

In addition to not disturbing radio services, the R&TTE Directive is concerned with both safety and EMC, and incorporates many of the requirements contained within the LVD and EMC Directives.

- EU web site for the R&TTE Directive: http://ec.europa.eu/enterprise/sectors/rtte/regulatory-framework/index_en.htm

3.6 Pressure Equipment Directive (97/23/EC)

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 reaction vessels, pressurised storage containers, heat exchangers, shell and water tube boilers, industrial pipework, safety devices and pressure accessories.

Further information on the above and other pressure equipment directives is available at: http://ec.europa.eu/enterprise/sectors/pressure-and-gas/pressure-equipment/index_en.htm

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, and other relevant information.

4.1 RoHS Directive (2002/95/EC and 2011/65/EU)

NOTE The recast RoHS Directive (2011/65/EU) will replace the original RoHS Directive (2002/95/EC) on 03 January 2013.

The Restriction of Hazardous Substances (RoHS) Directive restricts the use of lead, mercury, cadmium, hexavalent chromium, PBB (polybrominated biphenyls), and PBDE (polybrominated diphenyl ethers) 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:
http://ec.europa.eu/environment/waste/rohs_eee/legis_en.htm

4.2 WEEE Directive (2002/96/EC)

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" are excluded.

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

4.3 REACH Regulation (1907/2006)

Under REACH (Registration, Evaluation and Authorization 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.

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:
http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm

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) (Commission Regulation (EC) No 640/2009)
- Fans driven by motors with an electric input power between 125 W and 500 kW (Commission Regulation (EU) No 327/2011)

Ecodesign requirements are also under consideration for other equipment including:

- Compressors, including small compressors, and their possible drives
- Machine tools
- Industrial and laboratory furnaces and ovens
- Commercial refrigeration

EU web site for the Ecodesign Directive:
http://ec.europa.eu/enterprise/policies/sustainable-business/ecodesign/index_en.htm

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)

The Packaging and Packaging Waste Directive covers packaging and packaging waste.

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

5. Use of Work Equipment Directive (2009/104/EC)

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 on the use of work equipment that implement the provisions of Directive 2009/104/EC "Minimum safety and health requirements for the use of work equipment by workers at work".

6. Product Liability Directive (85/374/EEC)

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 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.

Declarations of Conformity (DoC's) for Rockwell Automation products are available at:
http://www.rockwellautomation.com/products/certification/ce/index.html

These DoC's 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

Declarations of Conformity (DoC's) for Rockwell Automation products:
http://www.rockwellautomation.com/products/certification/ce/index.html

List of New Approach directives and references of harmonised standards:
http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards

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.

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Publication EUDIR-WP001A-EN-P – April 2012

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