The European Union’s (EU’s) new Machinery Directive (2006/42/EC) is almost here. Adopted by the European Parliament and the Council of Ministers in June 2006, it was enforced 20 days later. Since then, conformity experts have had about a year and a half to examine the documents for differences. On December 29, 2009, these new provisions will become effective and replace the current version of the Machinery Directive (98/37/EC).

Fortunately, we have already had some time to test the waters with respect to this new legislation. For the next two years, we will see members of the EU adopt them into national law. Until this adaptation period ends in December 2009, EU countries are still accepting the current Machinery Directive as applicable.

Those who will be most impacted by these changes are manufacturers of machines and machine assemblies, as well as machine importers. Specifically, manufacturers of partly complete machines must abide by the Machinery Directive and issue a Declaration of Incorporation. Additionally, the requirements for machine importers have also been expanded under this new legislation. Now they will need to have a technical file in Europe and, on the Declaration of Conformity, must list the machine manufacturer’s name and address, in addition to the authorized representative’s contact information in the EU (identical to what is required in the Low Voltage Directive (2006/95/EC), and the technical file contact.

Changes Address Circulation, Advancements and Safety

While the new Machinery Directive has several consistencies with the current version, there are several differences between the two — none of which can be considered radical. Overall, the new legislation focuses more on free circulation within the EU market, as well as on various health and safety rulings. More importantly, the new legislation clarifies many passages of text that were previously considered a challenge for conformity experts to interpret.

With this new directive, the EU addresses advancements in machinery that occurred after the current directive was implemented. As expected, the technology to produce or run machinery evolved and the current directive, as it was written, could not accommodate some of these technological leaps. Over the years, the Commission issued guides to update the current directive. Compliance experts also spent a considerable amount of time interpreting parts of the directive to make sure new technology could meet certification requirements. In time, this methodology had become an accepted part of the industry.
The new Machinery Directive (2006/42/EC) will act as an umbrella for harmonized safety standards, eliminate previously ambiguous text, and accommodate potential advances within the machinery industry. As such, we will find that the directive's language will be general enough to encompass anticipated changes in technology, and to consider a wide range of issues. The final list of harmonized standards under the new Machinery Directive is not yet known, but will be similar to what is now available.

The Current Machinery Directive (98/37/EC)
The development of the new Machinery Directive has been 30 years in the making. Some of the current directive dates as far back as the 1970s, but the most recent updates were implemented about 10 years ago. Most of these changes became law through implementation into national legislation of the directive's essential requirements, which took effect in 1993 with a two-year transitional period.

At the time, many in the industry were unclear about these new requirements. The Commission offered interpretive guides and additional training to aid compliance professionals. On January 1, 1995, the directive became mandatory. By this time, EU member states had time to work through questions regarding the provisions of the directive, and compliance specialists learned how to interpret and apply the directive's wording to the machinery at hand.

The evolution of machinery over the last decade has spawned new issues concerning health and safety, thereby providing further reason to update the directive. However, some wonder why it has taken over 10 years to update this legislation. Ultimately, it takes time to harmonize the directive and then transfer it into law in each of the member states.

As will be seen with the new Machinery Directive, it will take roughly three-and-a-half years for the new law to be adopted throughout the EU. After that happens, it is a time-intensive process to update the text. In fact, the more people who have an opinion about the legislation, the more time it will take to make further changes. As a result, we predict that the new Machinery Directive will be around for quite some time.

Major Changes to the New Machinery Directive
As previously mentioned, many of the changes found in the new Machinery Directive are clarifications of previous amendments to current directive, and still only define the minimum level of safety required for machines entering the EU marketplace. Upon review, compliance experts will ultimately need to look at six major changes in this updated directive. The areas most impacted concern changes to the Low Voltage Directive, Lifts, Essential Health and Safety Requirements, Conformity Assessment, Market Surveillance.

Low Voltage Directive (LVD, 2006/95/EC)
The Low Voltage Directive (LVD) covers electrical equipment designed for use with a voltage rating of between 50 and 1000 V for alternating current and between 75 and 1500 V for direct current.

Typically, the standard equipment covered under the LVD are household appliances (EN 60335 series of standards); information technology equipment such as PCs (EN 60950-1); or laboratory, measurement and control equipment (EN 61010-1).

The primary differences between the LVD and the Machinery Directive include devices' moving parts and the ranking of their risks. To sum, the risks involved with moving parts on a device are more severe under the Machinery Directive.

On the subject of “main risk,” the new Machinery Directive eliminates the gray area that used to exist between the Machinery and the Low Voltage Directives. Now, there are six defined categories of electrical machinery that are now specifically excluded from the scope of the Machinery Directive, and which must comply with the Low Voltage Directive. Those categories include:

- Domestic household appliances
- Audio and video equipment
- Information technology equipment
- Office machinery
- Low-voltage switchgear and control gear
- Electric motors

The office machinery category required special clarification. Manufacturers of those devices ran into problems during the certification process, depending on their jurisdiction in Europe. Within the first 12 - 18 months after the new directive is in place, the EU Commission will probably give some guidance on which devices are covered and where they fall within those categories.

There are numerous types of electrical machinery that do not fall into these categories, but which still pose some level of electrical risk. In that case, they must follow the Low Voltage Directive’s safety requirements. Additionally, this machinery must comply with the Machinery Directive regarding conformity assessment and market placement.

EN 6204-1, the standard that covers machinery’s electrical safety requirements, is the most useful standard when assessing the electrical compliance of machines.

Lift Directive (95/16/EC)
In effect since July 1, 1999, the Lift Directive oversees the design, manufacture and installation of lifts (elevators) and ensures their safety and free circulation within the EU market. As can be expected, lifts have become faster over the past decade, and updates to the directive have become more
ambiguous over time. The new Machinery Directive will include some essential clarifications to this section. Briefly, the Lift Directive will not consider lifts that are incapable of surpassing 0.15 m/s in speed. Equipment that does not reach this velocity will look to the Machinery Directive’s requirements instead.

These types of lifts are commonly not open to the public, and are more likely to be located at industrial sites, such as refineries or other larger industrial installations. These lifts are commonly used to bring workers to their workplace (i.e., maintenance personnel to the top of a tower on a drill platform), and could be considered an “accessory” to an existing machinery installation.

**Safety Components Annex**

Safety has become an overriding issue over the past decade, and the new Machinery Directive will deliver a detailed list of 17 safety components in a new Annex V. This particular list is distinct in that the EU’s Machinery Committee can update the range of safety components to cover new products. A sample of items on this list include:

- Logic units to ensure safety functions;
- Emergency stop devices;
- Locking landing doors;
- Devices to prevent falls referred to in Section 3.2 of Annex I to prevent the car from falling or unchecked upward movements;
- Overspeed limitation devices;
- Energy-accumulating shock absorbers (non-linear or with damping of the return movement) or energy-dissipating shock absorbers;
- Safety devices fitted to jacks of hydraulic power circuits used to prevent falls;
- Electric safety devices in the form of safety switches containing electronic components

The current Machinery Directive lists just five safety devices in section B of Annex IV, and the new, more detailed list in the new directive accounts for the added focus of such safety devices and functions.

**Essential Health and Safety Requirements**

There has been much discussion about the changes made to the directive’s health and safety requirements. In reality, these requirements are not drastic modifications but simply clarifications. The most significant alterations have been the following:

- The discussion of risk assessment is now clearer to avoid ambiguity;
- Risk requirements were added for machinery serving fixed landings to take into account newly expanded scope of construction site hoists and slow-moving lifts;
- Certain risk requirements for mobile machinery or machinery for lifting are now applicable to all machinery types;
- Noise and vibration emissions now have specific requirements;
- The integration of safety devices must now taking into account any reasonably foreseeable misuse of such devices;
- The different life phases have been detailed and do now include also transport, assembly, dismantling, disabling and scrapping beside the normal use phase.

The first item in Annex I (under General Principles) is now a statement about the necessity and the responsibility of a risk assessment. In the past, risk assessments were either documented in the machine’s final design stage or not at all. Therefore, the new requirement underscores the EU’s increased focus on the proper application of risk assessments.

Risk assessments also play a vital role in determining which safety requirements apply to the machine. We assume that the
Safety

EU Commission will implement stricter enforcement to ensure the correct application of risk assessments.

Studies show that the misuse of safety devices (i.e., unauthorized bypass for maintenance or service tasks) results in an increased number of accidents. The manufacturer must confirm that a deliberate bypass of safety functions can be avoided within reason. In the future, this requirement will probably need additional clarification from the EU Commission or from industry groups.

**Conformity Assessment Procedures**

Currently, the manufacturer can certify most machinery for conformity and that requirement will remain the same. Annex IV in the new directive provides a list of machinery categories that must comply with certain conformity assessment procedures. Fortunately, manufacturers of Annex IV machinery will now have many procedures from which to choose:

- If the machinery is designed according to harmonized standards and fulfills the directive’s requirements, the manufacturer can certify the product;

- For other Annex IV machinery, the manufacturer can choose either a review by a Notified Body (NB) or have its quality assurance system approved by an NB.

It is important to note that, under the new directive, EU member states constantly review NBs. If an NB does not pass muster, then the member state can withdraw or suspend the NB’s notification.

The full quality assurance route for manufacturers of Annex IV equipment, as indicated in Annex X, adds certification options for manufacturers and will therefore decrease a product’s time to market.

**Market Surveillance**

In the new directive, EU member states have clearly defined responsibilities regarding market surveillance. These measures were inspired by the General Product Safety Directive (GPSD), which oversees consumer health and safety. The ruling uses a systematic approach of market surveillance to encourage collaboration among EU authorities and ensure a high level of consumer protection.

The obligations include cooperation with market surveillance authorities and require confidentiality and transparency. Such rules help manufacturers maintain their competitiveness within the market, as well as keep EU member states neutral throughout the conformity assessment process.

After consultation with the Machinery Committee, the European Commission can also adopt a decision to prohibit or restrict a category of machines from being placed on the market if it might present a risk.

**Compliance Efforts Should Start Today**

Conformity experts may wonder how this new directive will impact current compliance efforts. As a quick comparison, we can look at what occurred when changes were made to the EMC and Low Voltage Directives – two directives similar to the new Machinery Directive. When they were replaced, the updates occurred with minimal impact to the industry. It can therefore be presumed that updates to the Machinery Directive will not significantly disrupt compliance efforts. The only caveat is that manufacturers should take the time now to evaluate the directive’s impact on their equipment, and to prepare accordingly before the new directive becomes mandatory.

However, for many companies, the question remains: When do I start designing my products to comply with the new Machinery Directive? The answer is now. Current harmonized standards may not fully comply with the new directive because of the changes to the essential health and safety requirements in Annex I. In addition, it cannot be assumed that EC type-examination certificates issued before December 29, 2009 will remain valid. In fact, these certificates will need to be updated to reference the new directive.

Manufacturers are encouraged to start adapting their products to the new Machinery Directive right now. From a legal standpoint, only machinery in compliance will be allowed to be sold within the EU. All others will be effectively blocked from the market. From a practical point of view, it is more cost-effective for manufacturers to begin designing according to the new requirements today, instead of making adjustments to their products in two years.

The same holds true for compliance professionals. It is a time-intensive and costly process to review, notify and/or CE mark products. The European Commission recommends that conformity experts begin reviewing certificates now to avoid a bottleneck in the months leading to the December 2009 deadline. Ultimately, it is a more effective use of resources to consider all of the new legislation today rather than repeat the process in two years.

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