PERINI JOURNAL

N° 34 - march 2010

SAFETY

Considerations on the new machinery directive

December 2009 marked the entry into force of the new Machinery Directive 2006/42/CE within the EU, through implementation on national level. It is a substantial novelty for machine manufacturers that is entwined with the modifications introduced by social directives on machine safety, and more explicitly of all equipment used for work, that constitutes a wider ensemble which also includes machines.

Alessandro Mazzeranghi – MECQ S.r.l.

Our intent in writing this article is to identify the important novelties of the new directive that concern the impact it has on the manufacturer and the user, and to try and understand how these novelties change the scenario of responsibilities on the one hand, and the technical and documentation scenario on the other.
Of course, the considerations that follow are based on the text of the directive and its guidelines without the support of judicial acts. Since there are some important passages whose interpretation can be ambiguous, some opinions may well be subject to revision.
In any case, if we adopt the prudent criteria of taking every precaution and supplying all the evidence so that at the end of the production process, the result is a machine characterized by the highest possible safety level, we feel that we cannot commit any errors of substance, but maybe just errors of form.

MACHINES, "PARTLY-COMPLETED-MACHINES" AND COMPLEX MACHINES. In the tissue field – both at the paper mill as well as at the converting – the terms "incomplete machine" and "Declaration IIb" have an almost sinister sound. In the past, a certain amount of confusion, mainly by users, has led to the use of machines that, in actual fact, were not CE marked even though they were launched on the market after the entry into force of the machine directive (which took place between 1995 and 1996 according to the date of the various implementations on national level). Let's try and describe the panorama that existed in order to supply evidence of the considerable improvements that the new directive brings with it. To CE certify and mark a machine, the manufacturer had to supply something that had a clearly defined production purpose, and which, at the time, answered all applicable requisites of the machine directive and of the other directives pertinent to the machine in reference (for example, low tension directive, electromagnetic compatibility directive, etc.).
If the object of the supply was not able to autonomously fulfill a clearly defined application, or if it did not possess a portion of the protections, it could not be CE certified and marked. The manufacturer had to supply evidence of this situation through the so-called Declaration IIb (Annex II, letter b), also defined as the manufacturer's declaration. Some examples: a printing unit, a flow box, a roll conveyor belt, etc.; all cases where the object of the supply did not fit (and still does not fit) the definition of machine, and hence could not be certified and marked IIb were, absurdly, retained by users as constituting a normal declaration of conformity, and hence they could not understand they were starting up a machine that was not certified. And what's more, the forms required for the manufacturer's declaration were often made for a veritable declaration of non-conformity (as was well defined in the machine directive guide) which in fact exonerated the manufacturer and transferred all the responsibility to those who certified (or should have certified) the machine (which often turned out to be the user company). We should say that laws concerning this aspect are abundant and have always favored the interpretation of the guidelines.
This situation of basic status of indemnity from responsibility on the part of the producer in the case of incomplete machines, judicially well expressed in the contents of Declaration IIb, is a clear technical contradiction of terms: who more that the designer himself, is able to assess the safety level of a given incomplete machine, and is hence able to detect the best improvements in order to reduce risks to a minimum?

IN THE CORRECTION OF THIS ABNORMALITY LIES THE MOST IMPORTANT CONTENT OF THIS NEW NORM: through the concept of "partly-completed-machine", each manufacturer is responsible for the safety of what he or she places on the market, within the limits of the definition of the supply. Here, we must give the exact definitions of the directive (article 2 of Machinery Directive 2006/42/CE):
"For the purposes of this Directive, 'machinery' means:
- an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application,
- an assembly referred to in the first indent, missing only the components to connect it on site or to sources of energy and motion,
- an assembly referred to in the first and second indent, ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure,
- assemblies of machinery referred to in the first, second and third indent or "partly-completed-machinery" referred to in point (g) which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole,
- an assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort; (…)
For the purposes of this directive, "partly-completed-machinery" means an assembly which is almost machinery but which cannot in itself perform a specific application. A drive system is a partly-completed-machine. Partly-completed-machinery is only intended to be incorporated into or assembled with other machinery or other partly-completed-machinery or equipment, thereby forming machinery to which this Directive applies."
Please excuse the long quotation, but many parts of it will be useful in the course of this article. Here we can see, then, that a rather precise definition is given to "partly-completed machine", contrary to what was done in directive 98/37/CE, which gave no definition of "partly completed machine". It remains to be seen, however, through two excerpts from Annex II, what the manufacturer must declare regarding machines and "partly-completed-machines", respectively:
"A. Content of the CE declaration of conformity of the machinery (…)
- a sentence expressly declaring that the machinery fulfils all the relevant provisions of this Directive and where appropriate, a similar sentence declaring the conformity with other Community Directives; (…)
B. Declaration of incorporation of partly-completed-machinery (…)
- a sentence declaring which essential requirements of this Directive are applied and fulfilled and that the relevant technical documentation is compiled in accordance with part B of Annex VII, and, where appropriate, a sentence declaring the conformity of the "partly-completed-machinery" with other relevant Community Directives." .

HENCE, AS WAS TRUE PREVIOUSLY, ANYONE PLACING A MACHINE ON THE MARKET MUST DECLARE ITS CONFORMITY TO ALL APPLICABLE PROVISIONS OF THE DIRECTIVE. But those who place a "partly-completed-machine" on the market must declare explicitly to which provisions it conforms to, hence assuming a precise design and manufacturing responsibility regarding what he or she is declaring.
But here, too, not everything is perfect: for example, if a manufacturer of a "partly-completed-machine" protects (for objective reasons) only a portion of the potentially dangerous moving parts, what does this person declare in reference to requisite 1.3.7 of Annex I of the directive?
Of course, he or she cannot declare that he is fully respecting it, and consequently he should not declare anything at all… that would not be giving proof of what has been done towards safety, forcing those who must then certify the machine into taking on a wider responsibility with respect to what is technically necessary or reasonable. The author of this article is sure – after having discussed the topic at length with interested parties – that those manufacturers most attentive to customer satisfaction will find intermediate ways (for example, they will declare the respect of a given requisite limited to certain areas or elements of the "partly-completed-machine"), but it certainly is the task of the purchasers to pay particular attention to this aspect, defining, if need be, precise contract modifications, if they want to be sure to avoid unpleasant surprises.

DATE OF CERTIFICATION AND CE MARKING. Another extremely interesting aspect, it, too, deeply connected to the certification process rather than to the technical aspects of safety, is that of the CE marking date. Given that CE marking is an event that logically follows certification and not vice-versa, because the possibility of CE marking necessarily descends from the fact that an individual in the company possessing the proper authority (power to represent the company before external parties) has declared that, on the basis of the necessary evidence collected, the machine (or the "partly-completed-machine") is in conformity of given requisites, it must be noted that never before the proper date of certification had been defined. Personally, the necessary connection between the

 © Copyright Perini Journal

moment of certification and the launch on the market intended as the initial placement of the machine for sale or its being made available in the territory of the European Union, was not detected. Surely it was clear that certification and CE marking must have come before its launch on the market; but how long before? The same day, a month before, a year... what considerations had to be made?
Let's consider the electrical utensils that we use in the company: flexible pipes, drills, grinding wheels, etc... These are all small machines produced in series in large lots that can remain in warehouses – even those of the manufacturer – for a long time before they are sold to a retailer or to the final customer. Evidently, these objects are manufactured in conformity to the directives and norms in force at the time of manufacture, hence if they remain in the warehouse for such a long period of time as to witness a change in legislation and norms, how would they have to be dealt with? With directive 98/37/CE, this doubt was legitimate... now, thanks to the legislator, the problem is resolved through section 1.7.3 of the directive:
All machinery must be marked visibly, legibly and indelibly with the following minimum particulars: (...)
- the year of construction, that is the year in which the manufacturing process is completed.
It is prohibited to pre-date or post-date the machinery when affixing the CE marking.
It is an optimal principle, even though the issue of what is meant by 'completion of the manufacturing process' of complex machinery such as a tissue converting line must still be clarified: does it refer to the check-out at the manufacturer's plant or its commissioning at the customer's premises? [1]

WHO CERTIFIES THE MACHINERY? That is: who signs the declaration of conformity? With the previous directive, the answer was clear: it had to be a legal representative per force. Unfortunately, however, many companies had misunderstood this and had assigned the burden of signing the declarations to individuals such as the director of the technical department, the project designer, the sales director or others who had no power to represent the company; were such declarations valid? In theory, no. Hence, ultimately, machines having no CE marking were sold and used. In practice, we do not find evidence that the validity of these declarations has ever been doubted in any court, at least as far as the responsibility of the user is concerned. Instead, for what concerns the penal aspects, it was and is clear that the signature of a third party does not exclude the company's legal representative from his or her responsibility (as the final guarantor plenipotentiary) regarding the machinery's conformity.
Directive 2006/42/CE clarifies this issue, too, at Section 10 of Annex II, and states that the declaration of conformity must contain: (...) the identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorized representative. Hence, the person signing must be an individual authorized by the manufacturer, that is, possessing the required power of representation conferred by the company's management. The same, of course, is true for the declarations accompanying a "partly-completed-machine".

THE CENTRAL IMPORTANCE OF RISK ASSESSMENT. One last important clarification of the new directive concerns the need to assess the risks. This comes to constitute both the main instrument in safety design as well as the pivoting instrument of the technical dossier. And here, too, we cannot say that Directive 98/37/CE was wrong, but rather that it was not very clear. Indeed, risk assessment was not mentioned in the directive itself, but only in the technical norms (EN 1050 now EN 14121-1), hence the issue may well have seemed non-binding, while instead the cross-reference – where the technical dossier was mentioned – to the information regarding the essential requisites respected by the machinery, was strong.
Before we continue, we must understand that the requisites indeed constitute information regarding which solutions must be adopted when speaking about certain risks detected as present on the machinery. So starting from the requisites is basically approaching the issue from the opposite side: we speak about the possible solutions before having established exactly what the problems are and which level of criticality is associated with them. The result? Very simple: all risks are placed on the same level, without a clear priority as to the interventions.
Instead, the new directive states, at Section 1 of the General Principles of Annex I:
The manufacturer of machinery or his authorized representative must ensure that a risk assessment is carried out in order to determine the health and safety requirements which apply to the machinery. The machinery must then be designed and constructed taking into account the results of the risk assessment.
By the iterative process of risk assessment and risk reduction referred to above, the manufacturer or his authorized representative shall:
- determine the limits of the machinery, which include the intended use and any reasonably foreseeable misuse thereof,
- identify the hazards that can be generated by the machinery and the associated hazardous situations,
- estimate the risks, taking into account the severity of the possible injury or damage to health and the probability of its occurrence,
- evaluate the risks, with a view to determining whether risk reduction is required, in accordance with the objective of

 © Copyright Perini Journal

this Directive,
- eliminate the hazards or reduce the risks associated with these hazards by application of protective measures, in the order of priority established in section 1.1.2(b).
First of all the design engineer must detect the hazards and assess the risks, according to the terms previously established by EN 1050 (but not by the directive).
Clearly, since it is part of the technical dossier, risk assessment must be precisely documented so that later on, anyone can reconstruct the rationale that the project engineer used during the design phase.

CONCLUSIONS. We have seen here only the main novelties introduced by the directive, but we believe that the legislator's intent is in any case clear.
It is to resolve the main problems introduced by the previous directive – which were due essentially to defects in language – in order to turn the new directive into an unquestionable instrument that renders the manufacturer and the design engineer more responsible.
And it is in this key that the emphasis highlighted in Annex I – the main instrument for design and safety – of the directive on risk assessment must be read, too.
The level of protection of the user who thus receives clear indications on the conformity of the supply, whether it be a machine or a "partly-completed-machine", is therefore enhanced.
There is no doubt, then, that the directive represents a considerable step ahead that leads to an increasing, more precise study of safety by all those who are part of the chain that spans from the design phase to the final check-out of machinery, transferring the technical details to the harmonized norms that, as is well known, are much more flexible instruments when it comes to eventual revisions and updates. •

[1] We can surely state that the check-out constitutes an integral part of the manufacturing process (hence we cannot sustain that the end of the assembly phase is the end of the manufacturing process, if, for that particular machine, a check-out is expected). We have expressly used the phrase "commissioning at the customer's premises" in order to give an ambiguous definition that lends itself to two interpretations: final check-outs (hence manufacturing) or mere assessment of the correct placement in operation of the completely manufactured machine.

© Copyright Perini Journal