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Devices in Switching and Safety Technology

Principles of Market Access in Various Regions of the World

German Electrical and Electronic Manufacturers' Association

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Principles of Market Access in Various Regions of the World

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Content

1. Introduction

The subject of functional safety is gaining importance, not just in Europe but also in many other regions of the world. After all, every industrial process incorporates a risk of harming people, damaging production plants or polluting the environment. It is therefore easily seen in more and more regions of this world that regulations and laws are being passed to enhance the safety of machines and production lines. Safety-related automation plays a key role here.

Fig. 1: Typical market access models

- **Liberal market access within manufacturer's own responsibility**
  Example: European economic area
- **Restrictive market access**
  - Product approval with obligatory certification
  - Obligation to observe standards or other technical specifications
  - State (only) regulates on entry to market (at customs)

  Example: Electrical products in China, India
- **Open market access but strict rules on occupational safety**
  - No product requirements when importing and selling
  - No market surveillance
  - However: A test mark from a testing body is necessary on commissioning (operator specifications)
  - Possible additional requirements from local occupational safety authorities

  Example: US

Source: ZVEI

Fig. 2: Advantages and disadvantages of market access systems

"Manufacturer declaration" system	"Certification" system
+ Unbureaucratic	− Increased bureaucracy
+ No additional external administration costs	− Increased administrative costs
+ Quicker entry to market	− Delayed market entry
+ Flexible	− Low flexibility
+ Expert knowledge remains with the manufacturer	− Expert knowledge transfers to certifier
− Comprehensive testing competence is necessary at the manufacturer's facility	+ Manufacturer requires less testing
− Well-functioning market checks necessary	+ Possible reduction in liability for cases of damage (joint liability with the certifier?)
− CE mark is vague	+ Unsafe products are stopped at the source (but not with "black sheep")

Source: ZVEI

The world regions differ considerably however in their particular market access models. In some regions, a liberal market access is combined with a high individual responsibility from the manufacturer. In other countries, the market access is much more restrictive. Here, a product approval requires as a rule an obligatory certification and the binding application of the standards and technical specifications which apply in this part of the world. In still other parts of the world, an open market access exists, but there are strict rules on occupational safety. And overview of typical market models is shown in Fig. 1.

The various market access modules definitely have specific advantages and disadvantages for product manufacturers. In Fig. 2, a contrast is drawn between the important advantages and disadvantages of a relatively liberal and a restrictive market access system. Regardless of these advantages and disadvantages, each product manufacturer active on the global market must be thoroughly informed about the market access models applicable in the various parts of the world and orientate his in-house methods to the particular requirements. The question naturally arises here as to how far the individual process steps, risk assessments and, if applicable, product tests that are necessary for product approval in Germany, in part or even for the complete product approval, can be adopted in other parts of the world or have to be suitably modified. This brochure is intended to provide help in this assessment.

2. The situation in Europe

Author: Dr. Markus Winzenick (ZVEI)

History – legal background

Before the creation of a single market in Europe, each European country had its own national requirements for technical products. This resulted in a manufacturer in Germany, when exporting to neighbouring European countries, having to observe different requirements and sometimes very different legal and administrative regulations. In some cases, these different requirements also led to different product versions.

The 1957 Treaties of Rome to found the European Economic Community EEC which were then developed in several stages to the 2007 Lisbon Treaty to form the European Union of today, created a new situation in Europe. The Treaty on European Union (TEU) together with the Treaty on the Functioning of the European Union (TFEU) form the primary legal basis for the political systems of the EU.

The creation of a single market in Europe was laid down in Article 26 of the TFEU. Article 114 requires measures for harmonisation of legal and administrative regulations on the part of the member states which involve the setting up and functioning of the internal market. Directives were therefore decided which, together with the system of harmonised standardisation, led to the dismantling of trade barriers between the member states of the European Union. The principle of mutual recognition was also reinforced, which means that a product approved in one Member State must be approved for sale by the authorities in the other states. With the expansion of the European Union to 28 member states and the inclusion of three 3 EFTA states, the European Economic Area (EEA) is now the largest common market in the world.

What are the valid standards and laws?

- **Directive 2006/42/EC** of the European Parliament and of the Council dated 17 May 2006 on machines and the amendment to the Directive 95/16/EC (recast) (in short: **Machinery Directive**)

  The directive defines uniform safety regulations for the distribution of machinery on the market within the European Economic Area (EEA) as well as Switzerland and Turkey. Fundamental safety requirements are described in Annex I of the directive.

  The drafting of the safety requirements takes place via the harmonised standards with presumption of conformity. This means that the manufacturer, with correct application of harmonised standards, can assume that the fundamental requirements of the corresponding EU directives are to be satisfied without further ado. Not all harmonised standards trigger the presumption of conformity; only those harmonised standards that are listed in the Official Journal of the EU. The implementation of the EU directives in Germany is anchored in the Equipment and Product Safety Act (ProdSG) in combination with the Machine Ordinance (9th Ordinance on Product Safety).

- **EN 62061:** *"Functional safety-related electrical, electronic and programmable electronic control systems"*

  This standard lays down the requirements and gives recommendations for the design, integration and validation of safety-related electrical, electronic and programmable electronic control systems (SRECS) for machines.

It does not define any requirements for the performance of non-electrical (e.g. hydraulic, pneumatic, electro-mechanical) safety-related control elements for machines.

- **EN ISO 13849-1:** *"Safety-related parts of control systems - Part 1 – General principles for design"*

  This standard may only be applied to SRP/CS (safety-related parts of control systems and all types of machines, regardless of the technology and energy used (electrical, hydraulic, pneumatic, mechanical etc.)).

  EN ISO 13849-1 also provides special requirements for SRP/CS with programmable electronic systems.

- **Current preparation of standard ISO/IEC 17305: Merging of safety standards ISO 13849 and IEC 62061**

  In a standards project currently running at ISO and IEC, the two standards ISO 13849 and EN IEC 62061 are to be combined by 2017. In terms of content, many aspects have been adopted in the standards draft. The new standard is however very strongly oriented towards the planning processes of the users. In general, it is expected that the planning and design of a safe machine is to be made easier for the person applying the standard as more possibilities for risk assessment have been granted to the user and the responsibilities/competencies have also been clearly regulated in the standard.

Brief characteristics:

- Fundamental safety requirements are defined in Annex I of the Machinery Directive.
- The design takes place via harmonised standards.
- The presumption of conformity is linked to the application of these harmonised standards.
- The application of standards is optional, i.e. deviating solutions are possible.
- Approvals or permits from the authorities for the placing on the market are basically not necessary.
- The manufacturer produces a declaration of conformity, a third-party certificate is not required.
- The product is designated with the CE mark, not with the test mark.
- An obligation to involve a third party ("notified body") is only for certain risk products.
- The role of the state is limited to market surveillance.

Where do the difficulties lie?

The liberal process of declaring conformity as the responsibility of the manufacturer within the EU has certainly been a model of success for the European product manufacturers. It enables a relatively non-bureaucratic and flexible method for a quick market introduction of new products without additional, external administrative costs. It is however exactly these advantages which also lead to difficulties, e.g.:

- **The large freedoms of the method are also accompanied by lack of knowledge, uncertainty and errors.**
  For example, the method requires a comprehensive testing competence from the manufacturer. Further difficulties arise from design and demarcation questions in the Machinery Directive. The demarcation and definition of a safety component according to the Machinery Directive therefore leads to discussions. The CE mark is also often misinterpreted as a sign of quality.
- **Injustice reigns on the world market in spite of the WTO.**
  SFor example, third-country manufacturers benefit from liberal market access to the EU, but not the European manufacturers in export from the EU.
- **The placement on the EU market is simple.**
  "Black sheep" and "cheapies" often have it too easy, as seen by European manufacturers, when the market surveillance is not consistent or not fast enough.

What does market surveillance by government look like?

Market surveillance by the government is not a characteristic of just one nation, but exists in all member states of the European Union. All member states nominate for this purpose the authorities responsible for market surveillance and define the tasks, powers and organisational provisions. Market surveillance in Germany is the responsibility of the competent authorities in the individual federal states. The Federal Institute for Occupational Safety and Health (BAuA) assumes a certain coordinating function here.

With the introduction of the new Machinery Directive, these authorities (previously known as factory inspectorates) were given wide-ranging powers. This means that these authorities can resort to suitable measures so that products which are not safe or do not conform, can be relocated or removed from the market. A search can be made on the website **www.icsms.org** for each region in Germany and in the individual EU member states for the competent market surveillance authorities and the corresponding contact partners.

3. The Situation in China

Author: Frank Schmidt (Schmersal)*

History – legal background*

While the industrialisation in Europe took more than 200 years, it was only in 1978/79 that China began to open up economically. The economy has been growing at an enormous rate since then. China can be called the "work bench of the world" and exports both consumer goods and, increasingly, capital goods. At the same time, the country imports plants and machinery on a large scale in order to produce the constantly growing quantities of consumer goods.

According to the "China National Statistical Yearbook" of 2011, China imported mechanical and electrical products to a value of more than $ 660 billion in 2011 (Note 1). German companies supplied goods to a value of € 66.6 billion to China in 2012 (Note 2). This means that China is the fifth most important export partner for Germany and it can be assumed that the importance of China as a market for the German economy will continue to increase.

The first directive for the control of safety for imported plants and machinery "Administrative rules for standards for imported electro-mechanical products" appeared in 1998. These rules are no longer applied today. The orientation is now much more towards the European Machinery Directive.

In addition, the normative requirements on machine safety are changing more quickly than in Europe as the controls applied country-wide are to be pushed through more quickly than in the European Union. With each new five-year plan, the directives, or competencies and target-setting of machine safety, can also be changed.

For German and European machine builders, the fact is important that the Machinery Directive 2006/42/EC and the associated CE mark are known in China and, to a certain extent, accepted. Chinese committees and individual persons are also involved in the relevant ISO and IEC committees.

However – and that must be clearly stated – a machine with the CE mark does not automatically meet the requirements of the Chinese market in terms of machinery safety. The machine builder must know and observe the relevant Chinese regulations in each case.

What are the valid standards and laws?

At the national level, there are five laws that are relevant to the import or engineering design of machinery:

- Standardisation Law
- Product Quality Law
- Import & Export Commodity Inspection Law
- Regulations on Compulsory Certification (CCC)
- Regulations on Safety Supervision of Special Equipment.

These standards are issued and maintained by the "State General Administration of Quality Supervision, Inspection and Quarantine" (AQSIQ). These are updated and extended by amendments several times per year.

The "Product Quality Law" (§ 27) contains, amongst other things, instructions on the correct labelling of imported machines.

There are around 28,000 national and cross-discipline standards in China – that makes an overview of the situation difficult. About 50 per cent of these standards refer to international or non-Chinese standards such as ANSI, DIN, IEC, ISO and JIS.

The nomenclature of all national, sector-independent standards begins with "GB". Standards so designated are binding. In addition, standards with the designation "GB/T" are not binding.

Fundamental international standards in machinery safety, e.g. ISO 12100 "Safety of machinery – General principles for design" (as GB/T 15706) and ISO 14121 "Safety of machinery – Principles of risk assessment" (as GB/T 16856), were adopted – although as non-binding standards – into the Chinese set of rules on machinery safety.

Each industrial sector standard has a separate designation; the standards for mechanical engineering begin with the letters "JB".

The "China Compulsory Certificate" (CCC) that places demands on the components of machines (and many other parts) and presupposes a corresponding certification is binding for bringing onto the market and the import of products affected into China. Complete machines are not subject to CCC certification, but the other components such as electrical drives, switching devices, safety switching devices and electrical cables do require certification. As the customs authorities are not oriented towards commodity codes during import, it is not determined, and also not checked, whether all CCC-liable components of a machine are appropriately certified. This can be a problem during the delivery of spare parts. The user should therefore develop a spare parts strategy. By the way, the local manufacturers of machinery components are also liable for meeting CCC requirements.

Where do the difficulties lie?

There is no clear division of competence in the various committees which issue regulations and specifications for machine safety and supervise these. The room for interpretation in the provisions of the regulations is correspondingly large.

The situation is even less clear as there are numerous regional and even local administrative regulations that also affect machinery safety. They certainly may not contradict high-ranking national regulations, can however contain more precise regulations in terms of implementation guidelines.

As standardisation in machinery safety is changing rapidly, the machine constructor must keep constantly up-to-date on information concerning changes. This applies, for example, to the upcoming (optional) certification of functional safety of machinery.

Particularly obscure from the exporter's point of view are the very large number of regional and local administrative regulations. Knowledge of these is required before a machine is supplied to the particular region or is specified for the delivery to that locality.

Brief characteristics:

- There is (still) no pronounced market surveillance, but there are checks by the customs authorities.
- Many international standards have been adopted into the Chinese regulations own machine safety, but are still not up to date.
- Machines do not have to be CCC certified, but is necessary for central machine components.
- In addition to the national and industrial sector standards, there are also numerous regional and company-internal standards.

What can be adopted directly from the Machinery Directive and what is to be redone?

From the above, it can be assumed that a machine with CE mark basically meets the requirements of the Chinese market in terms of machine safety. On this basis, it is to be checked which regulations apply in concrete terms and whether possible modifications are necessary to the machine.

This task is made easier by the fact that many ISO and IEC standards apply in China. There are corresponding mirror committees and the A-B-C structure of the European standards world has been adopted. There is a total (status: September 2013) of around 400 "harmonised" C-standards in China. In the country as a whole, however, there are about 28,000 standards.

What does market surveillance by government look like?

Market surveillance by the state is weak at the moment. The authorities are however working on such a system. Since 2013, there has also been are machinery safety certifier for machines produced in the country. It is performed on a voluntary basis by the CNCA authorities (State Administration for Certification & Accreditation). How far and when this will be extended to imported machines is not yet clear. The machine builder or supplier should keep himself continually informed about the state of things.

Notes

* The content of the following contribution was taken, in part, from an article in a book: Joachim Fröhlich, Tingqi Wang: Maschinensicherheit in China (Machinery safety in China). In: Frank Schmidt (Ed.), Maschinensicherheit in Europa – Neues zum Thema Sicherheit von Maschinen und Maschinensteuerungen (Machinery safety in Europe – innovations on the topic of safety of machines and machine control systems). Wuppertal 2013, ISBN 978-3-935966-25-2

Note 1:
The data come from: Joachim Fröhlich, Tingqi Wang: Maschinensicherheit in China (Machinery safety in China). In: Frank Schmidt (Hg.), Maschinensicherheit in Europa – Neues zum Thema Sicherheit von Maschinen und Maschinensteuerungen (Machinery safety – innovations on the topic of safety of machines and machine control systems), p. 277

Note 2:
Source: German Federal Statistical Office

4. The Situation in the US

Author: Carsten Gregorius (Phoenix Contact)

History – legal background

In the United States, safety requirements for plants and machinery are largely placed on the operators by means of occupational safety regulations. There are therefore also indirect requirements placed on the manufacturers of machinery and safety components, without which the legal requirements could not be achieved.

The US product liability law is however seen as a much greater risk for manufacturers. Very often, the impression is given that a manufacturer of a product must take all possible (and impossible) applications into account. Especially the high sums for damages make many manufacturers feel uneasy.

There are essentially three claims criteria which apply:

- **"Breach of Warranty"**
  - Contractual liability
  - Compare with warranty liability
- **"Negligence"**
  - Negligent breach of due diligence
  - Independent of fault-based liability
  - Onus of proof on the plaintiff, compare with § 823 BGB
- **"Strict Liability in Tort"**
  - Absolute liability
  - Prerequisite → product fault
  - Irrespective of liability, compare with German product liability law

A product fault includes both design errors but also errors in instruction and breach of a product monitoring duty.

What are the valid standards and laws?

Essential occupational safety regulations are described in the OSHA standards (Occupational Safety & Health Administration). These laws are directed primarily at the operator/user of goods such as machinery. The observance of these OSHA standards is obligatory.

The set of regulations OSHA 1910 – O (Machinery and Machine Guarding) is the special authority on machinery and safety devices.

To satisfy the OSHA regulations, ANSI (American National Standard Institute) product standards in particular are consulted, whose application is in principle optional. These so-called Recognized Test Standards are developed by private organisations and substantiate the requirements that can be derived from OSHA 1910 – O.

For the functional safety of machinery, ANSI B11.19 "Reliability of control systems" which refers to ISO 13849, is taken into account.

Safety requirements for electrical equipment are described in the National Electrical Code (NEC), which is published by the National Fire Protection Association (NFPA) as NFPA 70. From this, the NFPA 79 is referred to for the electrical equipment of machines, its content defining similar requirements as in EN 60204-1. There are however differences in detail to be observed, e.g. colouring of conductors.

The relevant UL standards (UL 508) that must be fulfilled by components used on machinery can also be derived from the OSHA standards. The proof is demonstrated by a nationally listed laboratory (NRTL) that tests or lists this product. The NRTLs are published by OSHA. Here are to be found organisations such as CSA, Intertek (ETL), TÜV Rheinland, TÜV Süd as well as UL itself.

In the UL certification, a difference is drawn between UL listed and UL recognized. While "UL listed" is awarded for finished products that can be directly installed, UL recognized is used for products that are not yet complete in their application.

Where do the difficulties lie?

The significance of ANSI standards plays an important role in purchase agreements. Although not legally mandatory, the ANSI standards in many cases are rendered essentially mandatory through contracts under private law. In addition, ANSI standards are very often called on for production liability cases in the context of civil law suits. It is therefore advisable to take the relevant ANSI standards into account when designing machinery.

The commissioning of electrical equipment, e.g. of a machine or plant, is authorised by the so-called AHJ (Authorities Having Jurisdiction). These are ordered as a rule by the local or trans-regional governmental authorities. In some cases, the AHJ is a direct employee of UL, in other cases they are independent.

Practical experience shows that extent and depth of testing can vary greatly – depending on AHJ and region. An early contact to AHJ by the end user is therefore advisable.

Brief characteristics:

- Essential obligatory occupational safety laws are described in the OSHA (Occupational Safety & Health Administration) standards which are directed at the operator.
- Requirements for the manufacturers of machinery and safety components result indirectly from the OSHA standards.
- ANSI standards are very often called on for production liability cases in the context of civil law suits.
- Although the application of ANSI standards is not legally mandatory, they receive a "quasi obligatory" character due to civil law contracts.
- In many cases, ANSI and UL standards deviate more or less strongly from international or European standards.
- There is no governmental market surveillance in the US. A test mark from an NRTL is necessary for the commissioning of a plant.

In almost all cases, the UL and ANSI standards deviate more or less strongly from the international or European standards. Efforts are however being made in several areas of American industry to adapt to the requirements of the IEC standards. A comparison of European standards with the US-specific standards is urgently recommended in all cases – also with regard to the stricter product liability law. The current version of EN ISO 12100 is also available with identical content in ANSI/ISO 12100. A formal acknowledgement of European type tests by NRTL does not fundamentally exist.

What can be adopted directly from the Machinery Directive and what is to be redone?

EU law allows a progressive procedure that exploits the advantages of a risk-based approach. This means in practice that a manufacturer, who would like to bring his product onto the market within the EEA, carries out a risk assessment and derives measures on this basis to reduce the risk to an acceptable level. This procedure is described both in the Machinery Directive and in the A-standard EN ISO 12100.

The procedure is described both in the Machinery Directive and in the A-standard EN ISO 12100.

This procedure as an approach to the actual placing of products on the US market is just as valid, as the ISO 12100 – described above – was also published as ANSI/ISO 12100.

The difference is to be seen in the product liability law. In contrast to Europe, the US product-liability law is regarded as involving a much higher risk.

Special attention should be given to the preparation of user documentation. As there is no skilled worker training in the US, it must be assumed that there is less prior knowledge than is usual in Germany. The instructions should therefore be described step by step. Attention should also be paid to the quality of the translation – carried out ideally by a native speaker.

Components used in machinery must have a test mark in accordance with UL 508.

What does market surveillance by government look like?

There is no governmental market surveillance in the US. A test mark from an NRTL is however necessary for the commissioning of a plant.

5. The Situation in Brazil

Author: Otto Görnemann (Sick)

History – legal background

The Brazilian government and many other South American countries base their requirements very strongly on the machinery safety in Europe and the US. There are also legal requirements for the import of machinery and components. Increasingly, the implementation of regulations and minimum safety requirements for occupational safety at the operator of the machines is strictly controlled. The assessment as to whether a machine has been safely built and installed is based on the application of national standards, which are in turn strongly oriented towards international and European standards. The legal requirements in Brazil are very different from those in the EU. Various Brazilian ministries and authorities issue regulations for the bringing of certain products onto the market. Some regulations require testing or certification by an appropriate body. These regulations are product-specific, e.g. for medical technology devices, machinery, plug and socket connectors for electrical mains supply etc.

What are the valid standards and laws?

Laws:

In Brazil there are two different regulation areas in the safety requirements for products. The legal requirements for this are defined by different authorities. The Ministry of Work and Employment (Ministerio do Trabalho e Emprego "MTE") passes the laws that concern the safety of machinery and the requirements for protection devices. The Ministry for Development, Industry and Foreign Trade (Ministério do Desenvolvimento, Indústria e Comércio Exterior MDICE) issues regulations on the quality of products. INMETRO (Instituto Nacional de Metrologia) is responsible for accrediting testing bodies and the certification of products.

Table 1: Legal basis and area of application

Application area	Law / Competent authorities
Safety of electrotechnical products – Plug and socket connectors for domestic and similar uses up to 250 V AC –	Consumer protection law (Statute 8078) Lei N° 8078 de defesa do Consumidor Portaria No. 019 and No. 085 MDICE by INMETRO
Occupational safety and machinery safety	Statute N° 6.514, of 22.12.1977 – Occupational safety statute LEI N° 6.514, DE 22 DE DEZEMBRO DE 1977 Chapter 5: Occupational safety and health protection Ministerio do Trabalho e Emprego
Safety of medical technology products	Resolução n° 444, de 31 de agosto de 1999 ANVISA – Agência Nacional de Vigilância Sanitária

Source: ZVEI

Both regulations cover all legally prescribed safety requirements of the products concerned.

The Statute N° 6.514 makes a provision in Article 161 for the seizure of, or operational ban (Interdição) on, the machinery concerned when there is an immediate, serious risk to the workers.

This can be applied for by the occupational safety authorities (Delegado Regional de Trabalho), labour inspectors (Auditores) or by the representatives of the employees. (The employer must continue to pay wages during the operating ban).

Furthermore, in Article 184, the manufacture, import, sale, renting out and use of plants and machinery which are not fitted with the necessary equipment for safe starting and stopping or the avoidance of occupational accidents are prohibited.

The statute for the protection of consumers "Código de Defesa do Consumidor", N° 8.078, of 11 September 1990 forbids the bringing onto the market of products or services which do not correspond to the NRs. The same statute establishes that, when appropriate technical standards do not exist, the Brazilian standards (NBR) issued by the Brazilian Association for technical standards (ABNT) are to be applied.

The "Normas Regulamentadoras" NR's:

The Brazilian regulating standards (NR: Normas Regulamentadoras) correspond to the European directives and possess the force of law in Brazil. The term "Norma Regulamentadora" is to be understood more as "regulation" and not confused with "standard" (Norma Técnica). The focus here of the NRs is on the avoidance of accidents at work and contains, in part, requirements for product safety. The regulation (Portaria) 3.214 of 8 June 1978 on chapter V of the "Consolidação das Leis do Trabalho" (CLT, consolidation of occupational safety statutes) regulates the acceptance and publication of technical standards ("Normas Regulamentadoras – NRs") and places these on the same legal level as laws.

NR12 (regulating standard 12) for machinery and devices regards the safety of machines and devices and is based both on the European Machinery Directive and on the international and European standards with additional country-specific requirements.

NR12 prohibits the manufacturer, import, sale, auctioning, renting out, handing over of any kind, exhibiting and use of machines and plants that do not correspond to the standard (§ 12.134).

NR12 in a considerably revised version since 17.12.2010 and last changed by decree of the MTE dated 9.12.2013, has 18 sections with general safety requirements and 12 attachments with machine-specific requirements, e.g. for presses or plastic injection moulding machines.

The machine operators have certain transition periods for the adaptation of their machines to the requirements of these specifications. These transitional periods depend on the type of machinery and are almost all already expired. No transitional period has been allowed for presses as these were already present in the legal regulations of the federal states. Old machines must be, in part, modernised so that they may be further used. This regulating standard shall be checked continuously by a tripartite commission (government, employees and employers).

Although sections of standards (e.g. ISO 13852) are depicted in the NR12, it cannot be assumed that the observance of these standards ensures conformity with NR12. On the contrary, only the part of the standard depicted is authoritative for the conformity.

At the moment, regulation for proof of conformity by certification and a labelling requirement for individual safety products being placed on the market is in preparation. This certification shall be carried out by the MTE and not by INMETRO and implemented as a change in the law. The aim of this measure is to remove products from the market which do not satisfy the acknowledged product standards (dangerous products).

In addition to NR12, NR10 should also be observed. NR10 regulates electrical systems and services associated with them. This NR is to be used mainly for electrical installations in operating facilities, but also on machines.

Standards

Technical standardisation in Brazil is carried out by the ABNT (Asociação Brasileira de Normas Técnicas). The ABNT is a member of AMN, ISO and IEC. ABNT processes national standards or adopts (unchanged in most cases) ISO and IEC standards. Brazilian standards are labelled with NBR. Similar to EN standards in the European Union, the South American common market MERCOSUL (Spanish Mercosur) has the so-called NM standards (Norma Mercosul). Mercosul standards are issued by the AMN (Asociación Mercosul de Normalización). Similar to the Vienna and Dresden agreements for CEN and CENELC, ANM is increasingly adopting the international ISO and IEC standards. These are then implemented in Brazilian standards by the ABNT.

Many of these standards implement the international and/or European standards in Brazil. Here, this can be a simple translation into Brazilian Portuguese or an adaptation with additional requirements, e.g. for injection moulding machines. This can sometimes lead to a machine built to harmonised European standards not being approved in Brazil. The argument here is that many such machines in Brazil are fitted out and operated manually, so setting a higher requirement. Most classical standards on machine safety are already available as NBRs, e.g. (EN) ISO 12100 as general principles of design, risk assessment and risk reduction as ABNT NBR ISO 12100:2013.

For functional safety, the standard ABNT NBR 14153:2013 is still valid, based on EN 954 but has important differences (modified risk graph). At the moment, a translation and acceptance of ISO 13849-1/-2 is being worked on and the first version is expected in 2016 although, according to the circles involved, the acceptance of the standard by users will require a longer period of time.

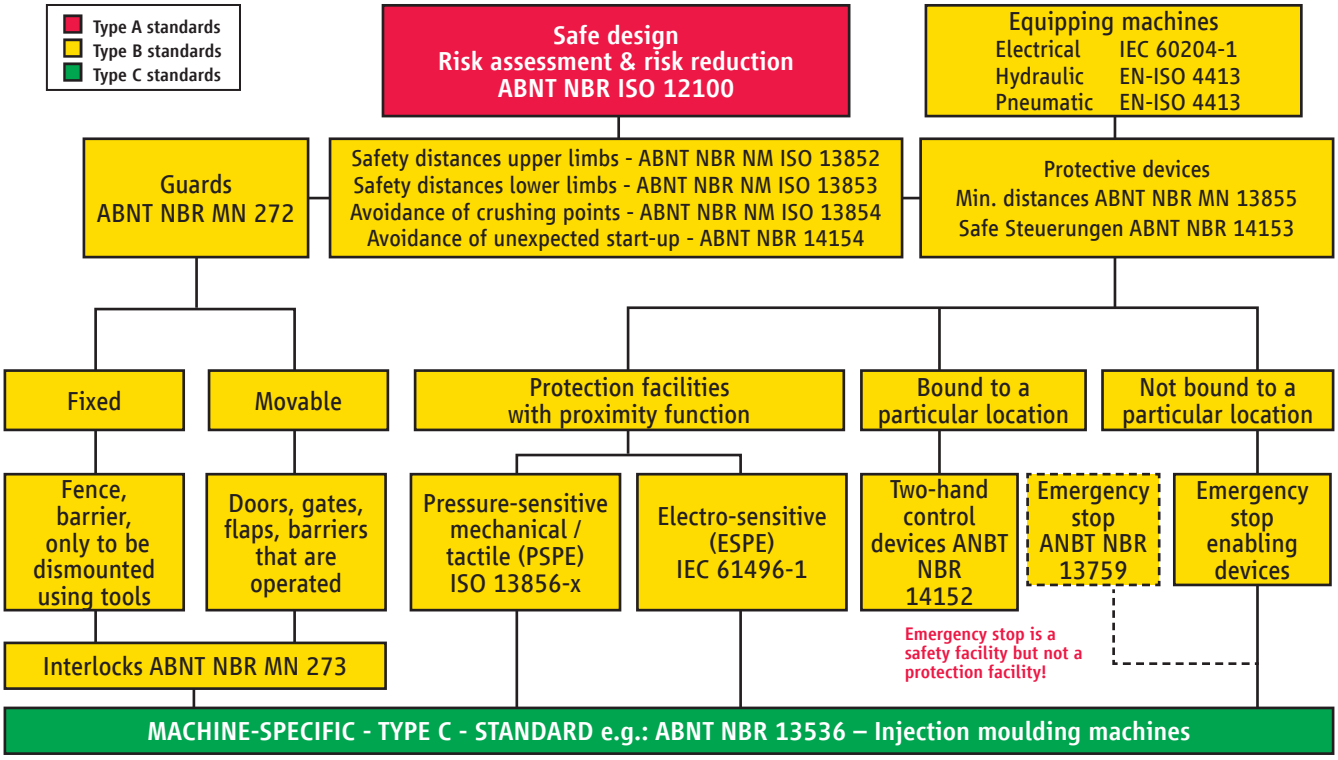
The observation of NBR standards is only obligatory when these are referred to by an NR. The observance of NBR standards is recommended as the occupational safety inspectors (Auditores) have large discretionary powers – similar to the AHJs (Authorities having jurisdiction) in the US.

NR12 references Brazilian and international standards in the very first section as below:

"This technical rule and its attachments define technical references, principles and protection measures in order to ensure the health and physical integrity of the employees and the minimum requirements for the prevention of accidents and occupational illnesses in the development phases and use of plants and machinery of all kinds as well as their manufacture, introduction, trading, exhibition and transfer in any way, in all commercial activities without prejudice to the provisions of all others by Government regulation N° 3214 of 8 June 1978 issued NR, as well as the official technical standards) and in the absence or omission of the same, to the applicable international standards."*

*) ABNT NBR's

Fig. 3: Overview of the fundamental safety standards for machinery in Brazil



Source: Sick

Brief characteristics:

- There exist legal regulations for the import of goods [Lei N° 8078 Art. 8] and indirectly for machinery and components [NR12 § 12.134].
- At the moment there is no general obligatory certification. In the future, an obligatory certification for a certain safety product is expected.
- Certifications by European and American institutes authorities are only accepted in the context of mutual acknowledgements.
- As a control, works inspections (also without prior notification) are possible.
- Valid international standards can only be applied when no national standards are available. These national standards have in part stricter requirements than the international standards.
- If there is an immediate and high risk for workers, an immediate operational (and sales) ban can be declared.

Where do the difficulties lie?

Brazil has at the moment one of the highest accident rates in the world. Unfortunately few occupational safety inspectors (Auditores) have an adequate technical training to enable a correct evaluation of the plants and machinery to be tested. Because of inexpert inspections, many unnecessary operational bans have been declared. Clear documentation in Brazilian Portuguese is especially important. Poorly executed documentation is a strong indication for the inspectors that NR12 is not being observed.

Many outdated, used machines are imported from EU, the US and even China which do not meet the requirements of NR12. Many new machines (from the above countries) are imported and operated without the necessary protection facilities. This leads to increasingly stringent interpretations of NR 12 by the inspectors.

Satisfying European standards (also harmonised standards) is certainly welcome, but does not guarantee conformity with the requirements NR12. It is strongly recommended to observe exactly these requirements.

What can be adopted directly from the Machinery Directive and what is to be redone?

The European Machinery Directive is a good basis. NR12 must however be analysed in detail and implemented. It places special demands on the operator in terms of documentation and training. The machine manufacturer should clearly regulate this requirement in the contract.

What does market surveillance by government look like?

The market surveillance takes place in that members of the occupational safety authorities make "surprise" factory visits. In this, the staff of the occupational safety authorities have the authority to shut down complete production lines until particular safety requirements have been met, or to confiscate the products. A release of the production line by the occupational safety authorities is then necessary. Reports appear in the press about such serious actions by the occupational safety authorities. In addition, the operator and machine manufacturer must face the threat of heavier fines if it is discovered, in the case of an accident, that the minimum requirements were not satisfied. In the individual case, the occupational safety authorities can also demand a certification by a third-party for certain components, even when no standard bindingly stipulates this. This can affect especially important components for machine safety.

It has also been reported many times that machines, which do not meet NR12 requirements but are declared as such, are regarded by Brazilian customs as "illicit goods" (Contrabando). The Brazilian customs then issues alerts to the customs authorities of other countries with which Brazil has bilateral customs agreements (e.g. US, Canada, China).

Further information:

Normas Regulamentadoras:
http://portal.mte.gov.br/legislacao/normas-regulamentadoras-1.htm

Brazilian standards (ABNT catalogue):
http://www.abntcatalogo.com.br/

6. Summary

Fig. 4: Technical market access conditions for essential electrical products

	Europe	China	US	Brazil
Compulsory certification with sign	(–)	+	(+)	(+)
(Quasi) monopole of the certification body	–	+	(+)	–
Obligatory works inspections (with follow-up inspections)	(–)	+	(+)	(+)
Property rights possible in standards	(–)	–	+	(–)
Specific national standards instead of international standards	(–)	(+)	+	(+)
Non-recognition of test results	–	(+)	(+)	(–)
Public "Black List"	(–)	(+)	(+)	(–)

Quelle: ZVEI

+ fully applies (+) applies mostly (–) does rather not apply – does not apply at all

As explained in the previous chapters, the subject of "Functional Safety" is gaining in importance worldwide. It is to be noted however that the particular regulations and market access conditions can be very different in the various regions of the world. While the market access for the sale of products in Europe is regulated very liberally from the manufacturer point of view, the requirements in Brazil, the US and China are regulated much more restrictively. A comparative overview is shown in Fig. 4. It applies generally that the formalised requirements in the European Machinery Directive and the harmonised standards listed there are also a good basis for the sale of plants and machinery for market access in other regions of the world.

In detail however, national standards and regulations which go beyond this are to be observed. There are however clear differences in the regulation of the principle of market surveillance in the various regions of the world. These range from more or less strongly emphasised surveillance by state authorities in Europe and China to the "surprise" factory visits by occupational safety and authorities in Brazil. In contrast, there is no comparable market surveillance in the US. In the event of damage however, horrendous claims for damages can be made against the distributors of plants and machinery.

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