

Machine Safety:

Harmonization of Standards Continues

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Europe and the U.S. maintain distinct machine safety standards, but a migration between these regions is beginning.

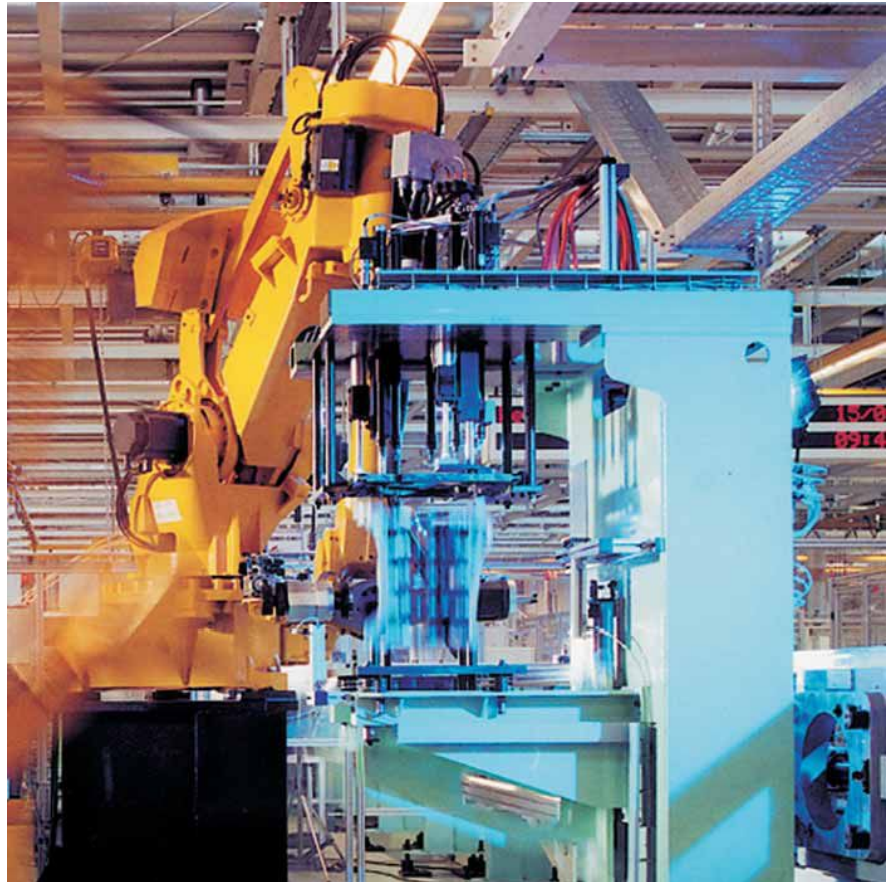
The goal of safety technology is to keep the potential hazards for people and the environment as low as possible by applying and using the appropriate technology.

Moreover, this goal needs to be achieved without imposing unnecessary restrictions on industrial production and the use of machines. In regions around the globe, there are different legal requirements regarding what has to be proven, and how, when determining whether there's sufficient safety. Likewise, the assignment of levels of responsibility can vary considerably. For example, in the European Community (EC) there are requirements, placed on both the manufacturer of a plant or system and on the operating company, that are regulated using the appropriate European Directives, Laws and Standards.

In the United States, requirements may differ both at the regional and local levels. However, throughout the country, there is a basic principle that an employer must guarantee a safe place of work. In the case of damage as the result of a product liability, manufacturers can be made liable due to the association with their product or products. What manufacturers of machines and plant construction firms must understand is that the legislation and/or rules of the location in which the machine or plant is being operated always apply. For example, the control system of a machine that's operated in the United States must fulfill U.S. requirements even if the machine manufacturer (i.e., OEM) is based in Europe. Even though the technical concepts with which safety is to be achieved are subject to clear technical principles, it is still important to find out whether legislation or specific restrictions apply.

In the following, we will compare and contrast some of the standards and regulations in Europe and the U.S. as they apply to machine safety. However, given the broad scope of this topic, we can only touch on some of the key standards. For a more detailed examination, go to <http://www.safetylink.com>

Some Basic Differences In the U.S., the two most influential safety related agencies/organizations are the Occupational Safety and Health Administration (OSHA)



and the American National Standards Institute (ANSI). Other industry-related organizations, such as the Robotics Industries Association (RIA), The Association for Manufacturing Technology (AMT), the Precision Metal Association (PMA), and so on, act as administrators/facilitators and provide support to groups such as ANSI. In addition, corporations as well as local and state regulatory agencies generate and/or oversee safety standards. OSHA, which was enacted by the U.S. Congress in 1970, is intended to help ensure the safety of workers and the protection of the nation's environment. The provisions of this act are mandatory and legally binding in the U.S. In terms of automatic machine safeguarding, OSHA has referenced safety standards written by the American National Standards Institute (ANSI) and the National Fire Protection Association (NFPA).

For several years now, a number of organizations throughout Europe have been involved in the development and/or enforcement of machine safety standards. As a result, European standards have been described as being more stringent and safety conscious than those in the U.S. While this may have been the case ten years ago, today the consensus is that the U.S. has largely caught up with Europe in regards to the

tightness of its safety regulations. U.S. standards are viewed as being application-oriented standards, as contrasted with Europe's product-oriented standards. However, they are regarded as being no less stringent and as effective as those of the European Community.

Functional Safety The differentiation between electrical safety and functional safety is reflected in the most recent standards—to the extent that there are special standards involved specifically with functional safety. The area of machinery safety addressed in EN 954 deals specifically with safety-relevant parts of control systems; therefore, it concentrates on functional safety. The IEC handles functional safety of electrical, electronic, and programmable electronic (E/E/PE) systems, independent of any specific application in the pilot standard IEC 61508. In IEC 61508, functional safety is defined as "part of the overall safety relating to the EUC [equipment under control] and the EUC control system which depends on the correct functioning of the E/E/PE safety-related systems, other technology safety-related systems and external risk reduction facilities." To achieve functional safety of a machine or a plant, the safety-relevant parts of the protective and control devices must function correctly, and, when a fault or failure occurs, the plant or system must remain in a safe condition, or be brought into a safe condition. To realize this, proven technology is required that fulfills the demands specified by the relevant standards. The requirements to achieve functional safety are based on the following goals: avoid systematic faults, control systematic faults, and control random faults or failures. The measure for the level of achieved functional safety is the probability of the occurrence of dangerous failures, the fault tolerance, and the quality that should be guaranteed by avoiding systematic faults. In the standards, this is expressed using various terms. For example, in IEC 61508 it's Safety Integrity Level (SIL), in EN 954 it's Categories, and in DIN V 19250 and DIN V VDE 0801 it's Requirement Classes (AK).

Current Requirements in the EC The requirements placed on health and safety at the workplace in the EC are based on Article 137 of the EC Contract. The Master Directive "Health and Safety of Personnel at the Workplace" (89/391/EC) specifies minimum requirements for safety at the work place. The actual requirements are subject to domestic legislation and can exceed the requirement of these Master Directives. The requirements are involved with the operation of products (e.g., machines) and not with their implementation.

Machinery Directive 98/37/EC With the introduction of a common European market, a decision was made to harmonize the national standards and regulations of the EC Member States. This meant that the Machinery Directive, as an internal Directive, had to be implemented in the domestic legislation of the individual Member States. In Germany, the contents of the Machinery Directive were implemented as the 9th Decree of the Equipment Safety law. For the Machinery Directive, this was realized with the objective of having

unified protective goals and to reduce trading barriers. The area of application of the Machinery Directive corresponds to its definition—that being, "Machinery means an assembly of linked parts or components, at least one of which moves..."—which encompasses a wide scope. With the Change Directives, the area of application has been subsequently extended to "safety components" and "interchangeable equipment." The Machinery Directive involves the implementation of machines. Machinery is also defined as "an assembly of machines that, in order to achieve the same end, are arranged and controlled so that they function as an integral whole." The application area of the Machinery Directive thus ranges from a basic machine to a complete plant. U.S. standards are viewed as being application-oriented standards, as contrasted with Europe's product-oriented Standards. The Machinery Directive has 14 Articles and seven Annexes. The basic health and safety requirements in Annex 1 of the Directive are mandatory for the safety of machinery. In selecting the most appropriate methods, the manufacturer must apply the following principles in the order given (Annex 1 Paragraph 1.1.2): a) "The machine design must guarantee that operation, equipping and maintenance, when the machine is correctly used, does not represent any potential danger to personnel." "The measure must exclude any risk of accident..." b) "When selecting the appropriate solutions, the manufacturer must apply the following basic philosophy, and, more specifically, in the specified sequence:

- Eliminate or reduce the risks as far as possible (integrating the safety concept into the development and the construction of the machine);
- Take the necessary protective measures against risks that cannot be eliminated.
- Inform users of the residual risks due to any shortcomings of the protection measures adopted." The protection goals must be responsibly implemented in order to fulfill the

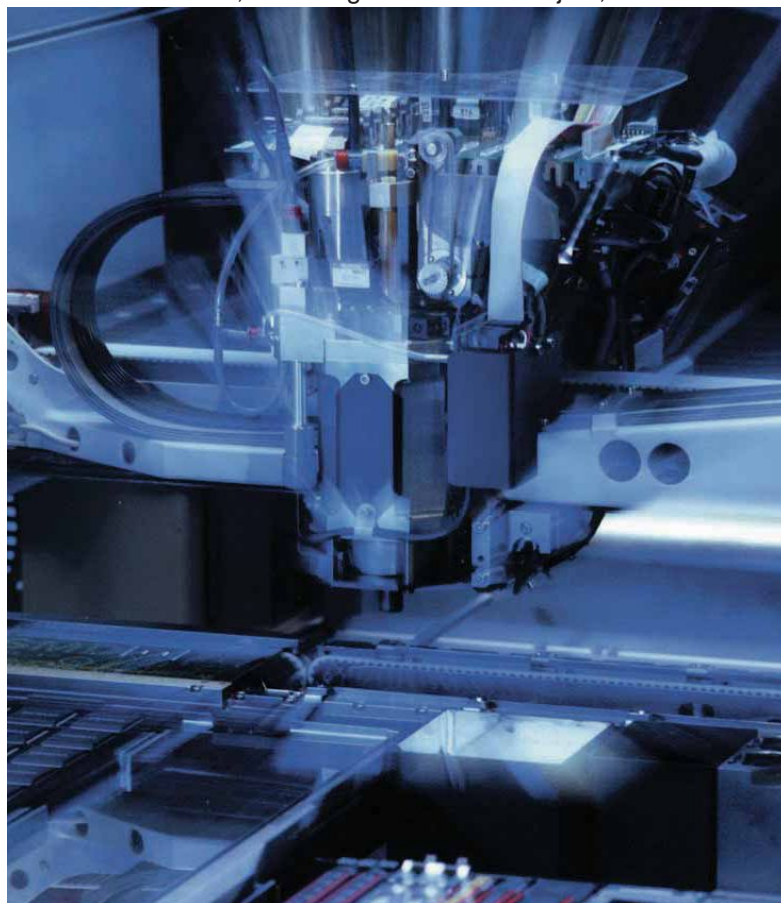


demand for conformance with the Directive. The manufacturer of a machine must prove that the basic requirements have been fulfilled. This proof is made easier by applying harmonized standards. A certification technique is required for machines listed in Annex IV of the Machinery Directive, which represent a more significant hazard potential. (Recommendation: Machinery which is not listed in Annex IV can also represent a high potential hazard and should be appropriately handled.) The precise “technique to define whether compliance exists” with the goals is defined in Chapter II of the Directive.

Standards To sell, market or operate/use products, these products must fulfill the basic safety requirements of the EC Directives. Standards can be extremely helpful when they involve fulfilling these safety requirements. In this case, a differentiation must be made between harmonized European standards and other standards that, although ratified, have still not been harmonized under a specific Directive, as well as other technical rules and regulations that are also known as “National Standards” in the Directives. Ratified standards describe recognized state-of-the-art technology. This means that by proving it has applied them, a manufacturer can prove that it has fulfilled what is a recognized state-of-the-art technology. Generally, all standards that have been ratified as European standards must be included, unchanged, in the domestic (national) standards of the Member States. This is independent of whether they are harmonized under a particular Directive or not. Existing national standards, handling the same subject, must

then be withdrawn. Thus, within a period of time in Europe, a unified set of regulations will be created (without any contradictions).

Occupational Safety and Health Administration (OSHA) Standards As we mentioned earlier, a significant difference between the legal requirements for safety at work between the U.S. and Europe is that, in the former, there is no unified legislation, across the country, which is applicable for the safety of machines, and which fully covers the responsibility of the manufacturer/ supplier. However, there is a general requirement that the employer provide a safe place of work. This is regulated with the Occupational Safety and Health Act (OSHA) of 1970. OSHA uses regional inspectors, who check whether the workplace fulfills the applicable regulations. The regulations, relevant for safety at work, of OSHA are defined and described in OSHA 29 CFR 1910.xxx (OSHA Regulations [29 CFR] PART 1910 Occupational Safety and Health). (CFR: Code of Federal Regulations). The core requirements of OSHA are listed in Section 5 (a) General Duty Clause. Each employer must set up a safety and health program to manage workplace safety and health to reduce injuries, illnesses, and fatalities by systematically achieving compliance with OSHA standards and the General Duty Clause. If it is not possible for the employer to comply immediately, the employer must develop a plan for coming into compliance as promptly as possible, which includes setting priorities and deadlines, and tracking progress in controlling hazards. Any hazard identified by the employer's hazard identification and assessment process that's covered by an OSHA standard or the General Duty Clause must be controlled as required by that standard or that clause, as appropriate. The application and use of various Standards is regulated in 29 CFR 1910.5 “Applicability of standards.” The concept is similar to that in Europe. Product-specific standards have priority over general standards as long as the associated aspects are actually handled there. When the standards are fulfilled, the employer can assume that he has fulfilled the core requirements of the OSHA Act regarding the aspects actually handled in the standard. Also per 1910.5 (f) “An employer who is in compliance with any standard in this part shall be deemed to be in compliance with the requirement of section 5(a)(1) of the Act, but only to the extent of the condition, practice, means, method, operation, or process covered by the standard.”



OSHA: Minimum Requirements The OSHA regulations define minimum requirements to guarantee safe places of employment. However, they should not prevent employers from applying innovative methods and techniques, e.g., state-of-the-art protective systems, in order to maximize the safety for employees. For specific applications, OSHA specifies that all of the electrical devices and equipment, which are used to protect the employee, be authorized for the application by a nationally recognized testing laboratory (NRTL), which has

been authorized by OSHA. In CFR 29 1910.6: "Incorporation by Reference," OSHA lists the non-government organizations that have developed standards that can be considered as mandatory OSHA requirements. In fact, 1910.6 spells out specifically that "organizations which are not agencies of the U.S. government which are incorporated in this reference in this part, have the same force and effect as other standards in this part." In other words, in the absence of OSHA standards, nonconformance to an ANSI guideline could result in an OSHA violation. Application And Use Of Additional Standards NFPA 70 (known as the National Electric Code) and NFPA 79 (Electrical Standard for Industrial Machinery) are two especially important standards regarding safety in industry. Both of these describe the basic requirements placed on the features and the implementation of electrical equipment. The National Electric Code (NFPA 70) predominantly applies to buildings, but also for the electrical connections from machines and parts of machines. NFPA 79 applies to machines. NFPA 79 NFPA 79 is valid for the electrical equipment of industrial machines with rated voltages of less than 600V. (A group of machines that operate together in a coordinated fashion is considered to be a machine.) The new Edition of NFPA 79 - 2002 includes some basic requirements for programmable electronics and buses, if these are used to execute safety-relevant functions. If these requirements are fulfilled, electronic controls and buses can also be used for Emergency Stop functions of Stop Categories 0 and 1 (refer to NFPA 79 - 2002 9.2.5.4.1.4). Contrary to EN 60204-1, NFPA 79 specifies that, for Emergency Stop functions, the electrical power must be disconnected using electromechanical devices. Requirements placed on programmable equipment and devices (refer to NFPA79 - 2002 11.3.4) include:

- Software and firmware-based controllers used for safety-relevant functions. These must be listed for such an application (this means, certified by an NRTL). In a note, a statement is made that IEC 61508 specifies the requirements to design such controllers. ANSI B11 is a consensus series of standards developed by consensus bodies such as the Association for Manufacturing Technology (AMT), National Fire Protection Association (NFPA), and the Robotic Industries Association (RIA). Risk assessment is a process used to evaluate the hazards of a machine. The risk assessment is an important requirement as specified in NFPA79 - 2002, ANSI/RIA 15.06 1999, ANSI B11.TR-3 and SEMI S10 (semiconductor). With the documented results of the risk assessment, one can then choose the appropriate safeguarding technique based on the given safety category of the application. The specific ANSI guidelines, which are of importance to the automatic machine safeguarding industry, are the ANSI B11 series. Of these, ANSI B11.19 - 1990 (Revised 1999):



"Performance Criteria for the Design, Construction, Care, and Operation of Safeguarding when Referenced by the Other ANSI B11 Machine Tool Safety Standards" has traditionally been of the most significance. In recent years, two other very important ANSI guidelines have taken on a great deal of significance. These are ANSI/RIA R 15.06-1999: "Industrial Robots and Robot Systems—Safety Requirements" and ANSI B11 TR3-2000: "Risk Assessment and Risk Reduction— A guide to Estimate, Evaluate and Reduce Risks Associated with Machine Tools." ANSI B11 TR 3-2000 is actually designated as a technical report by ANSI, but its impact has been, and will continue to be, significant. Risk Assessment Analysis Release of ANSI RIA 15.06- 1999 and of ANSI B11 TR 3-2000 brought about the potential for a trend towards increased use of third parties to accomplish these services. While part of current ongoing requirements, the full force of 15.06 and TR 3 have yet to be felt. Users, vendors and third-party services providers alike are gearing up for this application-

oriented approach to machine safeguarding. Risk assessment is intended to provide application-oriented evaluation of risk and reduction prior to an application being put into service. It also spreads the risk associated with machine safety among the manufacturer, third-party service provider (if any) and the user. In the past, the user had ultimate liability responsibility, although the manufacturers and third-party service providers were certainly not entirely immune to it. Finally, it appears that the acceptance of international standards will be directed more towards compliance with procedures (such as risk assessment and industry consensus standards) that can be met with existing products, perhaps with some associated

certification. The second trend, risk assessment analysis, will only require product modifications if certain product classes or types are not compatible with risk reduction. This is not seen as likely because risk assessment is already underway and there have been no such indications.

More Harmonization Ahead The typical view among the most knowledgeable persons in the field of machine safety, including those who sit on safety committees or are representatives of these, is that there may never be a single set of standards that will be acceptable to all nations. However, they see international standards being developed that will be conditionally accepted, and will form the foundation of all other standards. They expect to see this harmonizing of standards because it is in the best interests of major users, such in the automotive, appliance, and aerospace industries. These individuals are working diligently on the various committees to make this happen.