

**ISO international safety standards: contents and trends**

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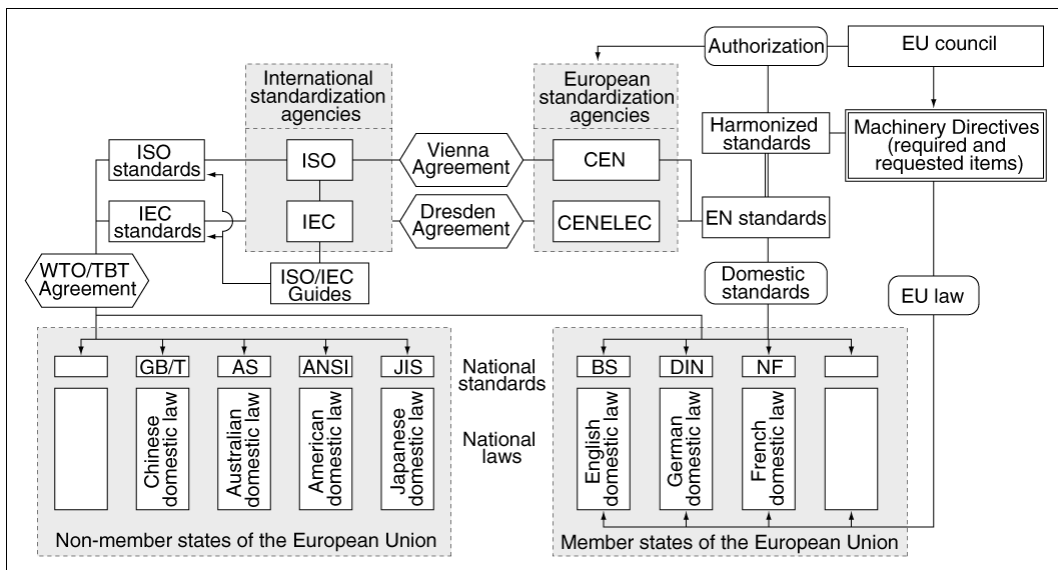
Upgrading and revising international safety standards is an ongoing process. This report presents a fresh overview of the international safety standards and summarizes current trends in revising those standards. This report will focus on the ISO international safety standards.

**1. ISO, EN and JIS**

Fig.1 shows how various standards are related, including the standards of the ISO (International Organization for Standardization) and the EN (European Standards), as well as the domestic standards of both member and non-members states of the European Union, and among them the JIS (Japan Industrial Standards). International safety standards have become standardized through the following process.

- (1)Enactment of Machinery Directives (1989)
- (2)Enactment of various EN-harmonized standards (EN 292, 1991; EN 954-1, 1996; EN 1050, 1996)
- (3)Enactment of international standards with EN serving as the drafts (ISO 12100, unpublished; ISO 13849-1, 1999; ISO 14121, 1999)

This sequence for standardization is stipulated by the Vienna Agreement, as set forth in item 2. Table 1 shows the documents drafted for each stage of the project within the ISO.



**Fig.1 Relationship among ISO, EN, and JIS<sup>1)</sup>**

**Table 1 Project stages and associated documents<sup>2)</sup>**

Project stage	Associated documents	
	Name	Abbreviation
0 Preliminary stage	Preliminary work item	PWI
1 Proposal stage	New work item proposal	NP
2 Preparatory stage	Working draft(s)	WD
3 Committee stage	Committee draft(s)	CD
4 Enquiry stage	Draft International Standard	DIS
5 Approval stage	Final Draft International Standard	FDIS
6 Publication stage	International Standard	-

## 2. Vienna Agreement

The Vienna Agreement (the ISO/CEN agreement on technological cooperation) is an agreement arranging mutual technological cooperation between ISO and CEN in the development of standards. The agreement was concluded in May, 1991. This pact mandated ISO and CEN joint reviews of standards and authorized CEN to create DIS ("draft international standards" in ISO).

Excerpt from the Vienna Agreement<sup>2)</sup>

4.3 ISO standard proposed for adoption with modifications

(a) (ii) If the ISO committee cannot or prefers not to prepare a revision of the ISO standard within the required European target dates, or for other reasons, the European Standard may be finalized in CEN according to 5.2 below. The amendments agreed within CEN will be offered to ISO by the CEN/CS for further harmonization (for instance, under the fast-track procedure).

Source: "Fundamental knowledge for ISO standards," Japanese Standards Association

In the IEC (International Electrotechnical Commission), when a vote is made on whether to approve or reject changes to the committee draft version (CDV, which corresponds to the DIS of the ISO, for which refer to Table 1), persons voting against a proposal must give a technical reason for their "no" vote, and so the right to propose a CDV is extremely significant. While I have not been able to confirm the rules governing voting in the ISO, even if this rule does not apply to that organization, the right to draft proposals would provide an extremely advantageous position.

This system puts non-Europeans at a disadvantage. When CEN creates a DIS (draft international standard), non-European countries, including Japan, are unable to become involved in planning the international standard before a DIS is submitted to ISO by CEN. This system is unable to ensure transparency, openness, and impartiality, and is lacking in "the principle of a process for creating international standards," and so Japan has proposed revising the system.

**3. International safety standards and the revision process**

- The following hierarchical structure of international safety standards is well known.
- (1) Level A standard = basic safety standard
  - (2) Level B standard = group safety standard (B1: safety elements common to various machinery; B2: safety related devices)
  - (3) Level C standard = product safety standard

The primary standards ranked as level A and B standards have been kept up to date fairly well, but the crucial ISO 12100 standards have remained at the international standards draft stage (DIS). The target date for official enactment is thought to be around 2003, but definitive information is not yet available.

On the other hand, the ISO standards in principle are to be revised every 5 years, and revision of standards already enacted is well under way. Since this also overlaps with the schedule for implementing the JIS standards, which are translated from the ISO standards, the situation becomes fairly complicated in Japan. Table 2 shows the enactment schedule for ISO, and table 3 shows the schedule for IEC.

**Table 2 ISO Standards**

Standards number	Publication date	Title
ISO/ DIS 12100-1	-	Safety of machinery--Basic concepts, general principles for design -- Part 1: Basic terminology, methodology
ISO/ DIS 12100-2	-	Safety of machinery--Basic concepts, general principles for design -- Part 2: Technical principles
ISO/AWI 13848	-	Safety of machinery--Terminology
ISO 13849-1	1999	Safety of machinery -- Safety-related parts of control system -- Part 1: General principles for design
ISO/ DIS 13849-2	-	Safety of machinery -- Safety-related parts of control system -- Part 2: Validation
ISO/TR 13849-100 (TYPE3)	-	Safety of machinery -- Safety-related parts of control system -- Part 100: Guidelines for the use and application of ISO 13849-1
ISO 13850	1996	Safety of machinery -- Emergency stop -- Principles for design
ISO 13851	2002	Safety of machinery -- Two-hand control devices -- Functional aspects and design principles
ISO 13852	1996	Safety of machinery -- Safety distances to prevent danger zones being reached by the upper limbs
ISO 13853	1998	Safety of machinery -- Safety distances to prevent danger zones being reached by the lower limbs

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Standards number	Publication date	Title
ISO 13854	1996	Safety of machinery -- Minimum gaps to avoid crushing of parts of the human body
ISO 13855	2002	Safety of machinery -- Positioning of protective equipment with respect to the approach speeds of parts of the human body
ISO 13856-1	2001	Safety of machinery -- Pressure-sensitive protective devices -- Part 1: General principles for design and testing of pressure-sensitive mats and pressure-sensitive floors
ISO 14118	2000	Safety of machinery -- Prevention of unexpected start-up
ISO 14119	1998	Safety of machinery -- Interlocking devices associated with guards -- Principles for design and selection
ISO 14120	2002	Safety of machinery -- Guards -- General requirements for the design and construction of fixed and movable guards
ISO 14121	1999	Safety of machinery -- Principles of risk assessment
ISO 14122-1	2001	Safety of machinery -- Permanent means of access to machinery -- Part 1: Choice of fixed means of access between two levels
ISO 14122-2	2001	Safety of machinery -- Permanent means of access to machinery -- Part 2: Working platforms and walkways
ISO 14122-3	2001	Safety of machinery -- Permanent means of access to machinery -- Part 3: Stairs, stepladders and guard-rails
ISO/ FDIS 14122-4	-	Safety of machinery -- Permanent means of access to machinery -- Part 4: Fixed ladders
ISO 14123-1	1998	Safety of machinery -- Reduction of risks to health from hazardous substances emitted by machinery -- Part 1: Principles and specifications for machinery manufacturers
ISO 14123-2	1998	Safety of machinery -- Reduction of risks to health from hazardous substances emitted by machinery -- Part 2: Methodology leading to verification procedures
ISO 14159	2002	Safety of machinery -- Hygiene requirements for the design of machinery

Resources: <http://www.iso.ch/>  
<http://www.jmf.or.jp/>  
<http://www.sostap.org/>

**Table 3 IEC Standards**

Standards number	Title
IEC 60204-1	Safety of machinery - Electrical equipment of machines - Part 1: General requirements
IEC 60204-11	Safety of machinery - Electrical equipment of machines - Part 11: Requirements for HV equipment for voltages above 1 000 V a.c. or 1 500 V d.c. and not exceeding 36 kV
IEC 60204-31	Safety of machinery - Electrical equipment of machines - Part 31: Particular safety and EMC requirements for sewing machines, units and systems
IEC 60204-32	Safety of machinery - Electrical equipment of machines - Part 32: Requirements for hoisting machines
IEC 61310-1	Safety of machinery - Indication, marking and actuation - Part 1: Requirements for visual, auditory and tactile signals
IEC 61310-2	Safety of machinery - Indication, marking and actuation - Part 2: Requirements for marking
IEC 61310-3	Safety of machinery - Indication, marking and actuation - Part 3: Requirements for the location and operation of actuators
IEC 61491	Electrical equipment of industrial machines - Serial data link for real-time communications between controls and drives
IEC 61496-1	Safety of machinery - Electrosensitive protective equipment - Part 1: General requirements and tests
IEC 61496-2	Safety of machinery - Electro-sensitive protective equipment - Part 2: Particular requirements for equipment using active opto-electronic protective devices (AOPDs)
IEC 61496-3	Safety of machinery - Electro-sensitive protective equipment - Part 3: Particular requirements for Active Opto-electronic Protective Devices responsive to Diffuse Reflection (AOPDDR)
IEC/CD 61496-4	Safety of machinery - Electro-sensitive protective equipment - Part 4: Passive infra-red protective devices (PIPDs)
IEC 61508-1 to 7	Functional Safety, Safety-related systems
IEC/CD 62046	Safety of machinery - Application of personnel sensing protection equipment to machinery (PSPE)

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#### 4. ISO and IEC Guide 51

The current ISO and IEC Guide 51 is the 1999 revised edition. This Guide is meant for persons drafting standards, and serves to present guidelines for implementing safety aspects into the standards. The fundamental concept of safety is established by clearly presenting the basic definition of safety and the concept of tolerable risk, and by laying out clear procedures for achieving these conditions. We will look more closely at these concepts below. These guidelines not only serve those persons responsible for drafting the standards, but also provide a basic frame of reference for everyone involved in all aspects of safety.

According to the definition in this Guide, it is not possible to have "safety" completely without risk. "Risk" is established as a combination of probability of injury and gravity of injury. A broad concept of "injury" is set forth including physical injury sustained by a person, injury to one's general health, or harm sustained by assets or environment.

Removing the restrictions of "absolute" from the definition of safety has made it possible to manage safety as a practical administrative target. However, this concept must be restrained by an ethical system that places high value on human life. Grave risk cannot be tolerated. It is crucial to have a strong awareness that even small risk cannot be treated lightly. Otherwise, we shall be saddled with the thorny question of who is permitting this "tolerable risk."

The Guide states that tolerable risk is attained through a process of risk assessment and risk reduction. This Guide does not go into concrete methods of performing risk assessment. Risk reduction is presented as a responsibility shared by designers and users.

The designer bears the responsibility for risk reduction using the following three-level strategy to be applied in order, with each step having priority over subsequent steps:

- (1) Inherently safe design
- (2) Protective measure
- (3) Information for use.

Product liability law stipulates that if some areas of danger remain after making a product as completely safe as possible, warning labels must be affixed for those areas. This is exactly the type of thing indicated in the risk reduction strategy.

When the results of risk assessment are obtained, the standard for determining if machinery can actually be used is "whether a tolerable level of risk has been attained." "Tolerable risk" is based upon the sense of values of society of a particular era, and denotes the acceptable level of risk. If we adhere to the rules of international standards, this acceptable level is determined as follows.

- (1) For products covered by level C standards, the manufacturer and administrator fundamentally fulfill their responsibility by carrying out policies determined in those standards.
- (2) For products not covered by level C standards, tolerability is determined based on the self-responsibility of the manufacturer and administrator. Whether or not that is appropriate can be determined by whether accidents occur in operation, and ultimately may be decided in a court of law.

## 5. ISO/FDIS 12100-1 and -2

ISO 12100-1 and -2 are at the very heart of the international safety standards, and bear the following official names

Machinery safety: General principles for fundamental concepts and design  
Section 1: Basic terminology and methodology  
Section 2: Technical principles and specifications

However, as of January 2003, these standards are still at the FDIS (final draft international standards) stage, and have not officially been published. These contents have been published as technical reports in JIS (Japan Industrial Standards) as TR B 0008 and 0009, translated from ISO/TR 12100-1 and -2.

### 5-1 ISO/TR 12100-1 (1992)

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Let's look at the main contents of this standard.

Machinery (machine) is defined as an assembly of linked parts or components, at least one of which moves, with appropriate machine actuators, control and power circuits, joined together for a specific application, in particular for the processing, treatment, moving or packaging of a material.

Safety of a machine is the ability of it to perform its function, to be transported, installed, adjusted, maintained, dismantled, and disposed of under conditions of intended use specified in the instruction handbook without causing injury or damage to health.

And then intended use is the use for which the machine is suited according to the information provided by the manufacturer or which is deemed usual according to its design, construction and function.

Intended use also involves the compliance with the technical instructions laid down notably in the instruction handbook, taking into account reasonably foreseeable misuse. The product liability law can be seen as extending protection to uses coinciding with "normal conditions of use."

The following four examples are given to show "foreseeable misuse."

- (1) Foreseeable incorrect behavior resulting from normal carelessness, but not resulting from deliberate misuse of the machine,
- (2) The reflex behavior of a person in case of malfunction, incident, failure, etc.,
- (3) Behavior resulting from taking "the line of least resistance" in carrying out a task,
- (4) For some machines (especially machines for non-professional use), the foreseeable behavior of certain persons, such as children or the disabled.

Machinery design covered by this standard refers to all of the following types of activity.

- (1) Construction
- (2) Transport and commissioning
- (3) Use (settings, teaching/programming/process changeover, operation, cleaning, fault finding, and maintenance)
- (4) De-commissioning, dismantling, and, as far as safety is concerned, disposal

Failsafe conditions (minimizing dangerous failure) are defined as theoretical conditions that provide the ability to maintain safety functions during a power outage, or when confronting conditions arising from the breakdown of any structural components. In reality, the creation of a failsafe system can be attained by combining elements that contain features of an asymmetrical failure mode. Some concrete strategies for risk reduction are also given, such as safety guards and control devices.

Subsequently, a number of examples of hazards are presented. These are the contents that are described in detail in part 6 of this report.

### **5-2 ISO/TR 12100-2 (1992)**

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This standard classifies risk reduction strategies into four categories. These strategies are presented in order of priority. In other words, the standard calls for the strategy with the lowest number to be tried first, and if that does not provide adequate results, the strategy with the next lowest number should be tried.

(1) Risk reduction by design

In this clause, two principles are adopted. Primarily, avoiding or reducing as many of the hazards as possible by suitable choice of design features. And secondarily, limiting persons' exposure to hazards by reducing the need for operator intervention in danger zones.

(2) Safeguarding

In this clause, various types of barriers and safety devices are described.

(3) Information for use

Information for use consists of communication links, such as texts, words, signs, signals, symbols or diagrams, used separately or in combination, to convey information to the user. However, this section states that information for use shall not compensate for design deficiencies.

(4) Additional precautions

In this clause, the following two measures are described:

(a) Emergency stopping devices and preparations for escape and rescue of trapped persons as precautions in view of emergency situations.

(b) Equipment contributing to safety, such as maintainability, isolation from power supplies, and energy dissipation.

### **5-3 Revision and publication of ISO 12100**

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The ISO 12100 standard is currently at the FDIS (final draft international standard) stage. Repeated revisions have been made from the 1992 publications of ISO/TR 12100-1 and -2, and this is expected to be published as an international standard in approximately 2003. Table 4 shows a comparison between the composition of recent draft standards and ISO/TR 12100-1, and table 5 shows a comparison with ISO/TR 12100-2.

A comparison of the 1992 publication with the latest draft version shows the following changes.

(1) ISO/FDIS 12100-1

This standard provides for protective strategies instituted by the user in addition to those protective strategies instituted by the designer. The standard also mandates information flow from the designer to the user as well as from the user to the designer.

(2) ISO/FDIS 12100-2

Machinery safety is not provided solely by the reliability of control systems, but also depends on the reliability of all the machinery parts, and so new points of reliability have been established. We should keep an eye on the revisions to ISO 13849 (discussed below) as it relates to trends in international machine safety.

**Table 4 12100-1**

ISO/TR12100-1:1992		ISO/FDIS 12100-1:2003	
1	Scope	1	Scope
2	Normative references	2	Normative references
3	Basic concepts	3	Terms and definitions
4	Description of hazards generated by machinery	4	Hazards to be taken into account when designing machinery
4.1	General	4.1	General
4.2	Mechanical hazard	4.2	Mechanical hazard
4.3	Electrical hazard	4.3	Electrical hazard
4.4	Thermal hazard	4.4	Thermal hazard
4.5	Hazards generated by noise	4.5	Hazards generated by noise
4.6	Hazards generated by vibration	4.6	Hazards generated by vibration
4.7	Hazards generated by radiation	4.7	Hazards generated by radiation
4.8	Hazards generated by materials and substances	4.8	Hazards generated by materials and substances
4.9	Hazards generated by neglecting ergonomic principles in machine design	4.9	Hazards generated by neglecting ergonomic principles in machine design
4.10	Hazards combinations	4.10	Hazard combinations
		4.11	Hazards associated with the environment in which the machine is used
5	Strategy for selecting safety measures	5	Strategy for risk reduction
5.1	Specification of the limits of the machine	5.1	Specification of the limits of the machine
		5.2	Hazard identification, risk estimation and risk evaluation
5.2	Systematic assessment of hazardous situations		
5.3	Removal of the hazards or limitation of the risk	5.3	Removal or reduction of the risk by intrinsic design measures
5.4	Safeguarding against hazards which could not be avoided or sufficiently limited according to 5.3	5.4	Risk reduction by safeguarding-Implementation of complementary protective measures
5.5	Informing and warning users about residual hazards	5.5	Risk reduction by information for use
5.6	Additional precautions		
5.7	Remarks		
6	Risk assessment		
6.1	Introduction		
6.2	Factors to be taken into account when assessing a risk		

**Table 5 12100-2**

	ISO/TR12100-2:1992		ISO/FDIS 12100-2:2003
1	Scope	1	Scope
2	Normative references	2	Normative references
3	Risk reduction by design	3	Intrinsic design measures
3.1	Avoiding sharp edges and corners, protruding parts, etc	3.1	Avoiding sharp edges and corners, protruding parts
3.2	Making machines inherently safe by virtue of...	3.2	Consideration of geometrical and physical factors
3.3	Taking into account design codes, data about material properties, etc	3.3	Taking into account the general technical knowledge regarding machine design and construction
3.4	Using inherently safe technologies, processes, energy supplies	3.4	Using intrinsically safe technologies, processes, power supplies
3.5	Applying the principle of the positive mechanical action of a component on another component	3.5	Applying the principle of the positive mechanical action of a component on another component
3.6	Observing ergonomic principles	3.6	Observing ergonomic principles
3.7	Applying safety principles when designing control systems	3.7	Applying intrinsic design measures to control systems
3.8	Preventing hazards from pneumatic and hydraulic equipment	3.8	Preventing hazards from pneumatic and hydraulic equipment
3.9	Preventing electrical hazard	3.10	Preventing electrical hazard
3.10	Limiting exposure to hazards through reliability of equipment	3.11	Limiting exposure to hazards through reliability of equipment
3.11	Limiting exposure to hazards through mechanization and automation of loading/unloading operations	3.12	Limiting exposure to hazards through mechanization or automation of loading (feeding) / unloading (removal) operations
3.12	Limiting exposure to hazards through location of the majority of setting and maintenance points outside the danger zones	3.13	Limiting exposure to hazards through location of the setting and maintenance points outside of danger zones
		3.14	Provisions for the maintainability of a machine
		3.15	Provisions for the stability of machines and their elements
4	Safeguarding	4	Safeguarding and complementary protective measures
		4.0	General
4.1	Selection of guards and safety devices	4.1	Selection and implementation of guards and protective devices

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	ISO/TR12100-2:1992		ISO/FDIS 12100-2:2003
4.2	Requirements for the design and construction of guards and safety devices	4.2	Requirements for the design and construction of guards and protective devices
		4.3	Complementary protective measures
		4.4	Protective measures reducing emission
5	Information for use	5	Information for use
5.1	General requirements	5.1	General requirements
5.2	Location and nature of information for use	5.2	Location and nature of the information for use
5.3	Signals and warning devices	5.3	Signals and warning devices
5.4	Markings, signs (pictograms), written warnings	5.4	Markings, signs (pictograms), written warnings
5.5	Accompanying documents	5.5	Accompanying documents (In particular, instruction handbook)
6	Additional precautions		
6.1	Precautions in view of emergency situations		
6.2	Equipment, systems and arrangements contributing to safety		

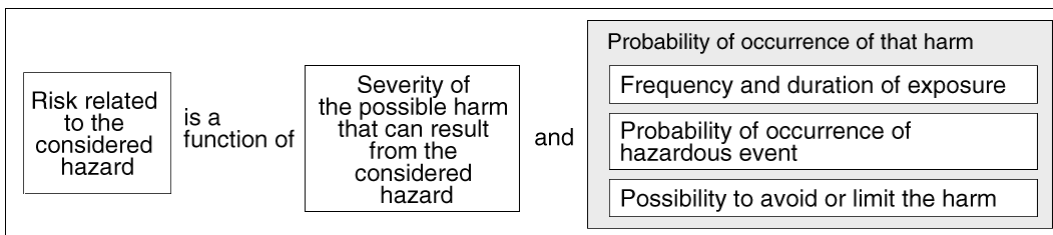
## 6. ISO 14121

ISO 14121 (Safety of machinery - Principles of risk assessment) has been positioned as a Type A standard, and it is important among the systems of international safety standards.

In this standard, risk consists of the following two elements (Fig.2).

This standard has the following two features.

- (1) Risk assessment procedures are defined as repetitive processes
  - determination of the limits of the machinery
  - hazard identification
  - risk estimation
  - risk evaluation
  - judgement if the machinery is safe
- (2) Hazards should be identified by referring to the table in Annex A.



**Fig.2 Elements of risk according to ISO 14121**

## 7. ISO 13849-1 Safety of machinery: safety-related parts of control systems Part 1: general principles for design

### 7-1 1999 publication

This important standard defines safety-related parts, level of safety categories, and categories to be adopted in accordance with the level of risk.

Safety-related part means a part or subpart of a control system that responds to input signals and generates safety-related output signals. The combined safety-related parts of a control system start at the points where the safety-related signals are initiated and end at the output of the power control elements, and this also includes monitoring systems. Categories are classifications of the safety-related parts of a control system associated with fault resistance to the fault (failure) and behavior of the system under fault (failure) conditions.

To select and design safety measures, the following procedures are provided. Since each step has a relationship to others, the adoption of safety measures is ultimately a repetitive process.

- (1) Step 1: Hazard analysis and risk assessment
- (2) Step 2: Determine risk reduction measures by control system
- (3) Step 3: Designate safety requirement for safety-related parts of control system
- (4) Step 4: Design
- (5) Step 5: Validation

As category requirements are well-known, they have been omitted.

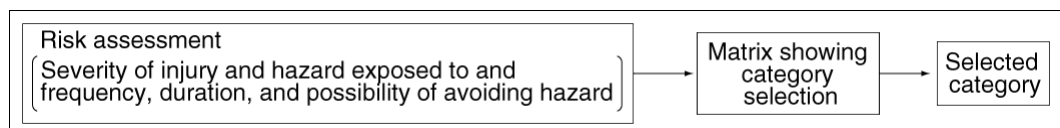
A major feature of this standard is that it defines "categories" and sets selection criteria for the categories of safety-related components relative to the level of risk. In this way, unified principles are created for matching the level of risk with the proper level of safety system.

Until this standard was created, analogous designs were made based on safety criteria (e.g., manufacturing standards) established for parts of the machinery. However, this does not mean that discrete safety criteria are well known. In industries employing machinery without established safety criteria, it is extremely difficult to find out about the significance of the safety criteria. Ultimately, unified safety designs cannot be created without basic principles. ISO 13849 represents the first attempt to create applicable criteria for unified safety strategies. (However, selection of the risk category in this standard as well is limited to referencing annexed documents.)

### 7-2 Revisions

The basis for this standard, EN 954-1, is currently undergoing revision. The draft of the revision makes major changes in procedures from graphing risk to selecting safety strategies. (For details, please refer to the article "A summary of trends in international safety standards and safety checking systems," in Espec Technology Report, Japanese version.)

In ISO 13849-1 (1999), as Fig.3 shows, unique categories are determined from risk assessments. (However, multiple candidates are presented.)

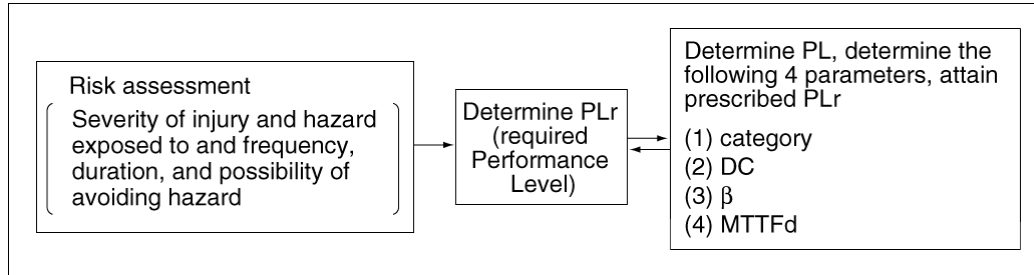


**Fig.3 Category selection according to ISO 13849 (1999)**

As Fig.4 shows, the currently under revision EN 954-1 determines risk assessment results and PLr (required Performance Level). However, the PL (Performance Level) is determined according to the following four parameters.

- (1) Category = same as current category
- (2) DC = Diagnostic Coverage (self-diagnosis ratio)
- (3)  $\beta$  = Common-Cause Factor (average probability of dangerous failure according to common factor malfunction)
- (4) MTTFd = Mean Time to Dangerous Failure

The PL (safety performance level) is determined by appropriately combining these four parameters. The target for selecting the safety strategy is based on making the PL reach the PLr.



**Fig.4 Selecting PL according to EN954-1 draft**

Table 6 shows the relationships for the PL (safety performance level), the average probability of dangerous failure, and the SIL (safety integrity level, IEC 61508).

**Table 6 Relationships for PL, average probability of dangerous failure, and SIL (IEC 61508)**

PL	Average Probability of a Dangerous Failure per Hour (1/h)	SIL
a	$10^{-5} < = PDF < 10^{-4}$	-
b	$3 \times 10^{-6} < = PDF < 10^{-5}$	1
c	$10^{-6} < = PDF < 3 \times 10^{-6}$	1
d	$10^{-7} < = PDF < 10^{-6}$	2
e	$10^{-8} < = PDF < 10^{-7}$	3

The concept of reliability and the methodology based on IEC 61508 has been broadly adopted. Currently, ISO 13849 allows for multiple categories in some cases, depending on the category selection criteria, but does not explicitly present the concrete selection criteria given here. The final draft of this revision establishes selection criteria based on reliability criteria.

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