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Axelent Safety

Risk Assessment in Mechanical Engineering

- Efficient
- Target-oriented
- Conforming to standards

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- conforming to standards

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1 Introduction

"Risk assessment" – mention of the word is enough to cause an allergic shock or a bad conscience in developers and machinery designers. Even more than 25 years after the introduction of CE marking for machinery numerous manufacturers still have not satisfactorily solved the "problem" risk assessment. Why is that?

The main reason is a lack of easy-to-learn, economical methods that would help remove risk assessment from the realm of "secret arts". This little brochure is meant to present such a method in brief and demonstrate its application.

2 Risk Assessment – Why?

When designing machinery, engineers primarily focus on function, efficiency and economic concerns. Safety rarely is of much concern, especially not at the early stages of a project. However, it may be very difficult to integrate safe operation into the overall functional and operating concept later on. In fact, safety measures added during the final stages of the project often impair accessibility and efficiency of the machinery.

What's in risk assessment?

- Specify functions of the machinery
- Identify hazards caused by the function
- Estimate risk involved (injury and probability occurrence)
- Seek to eliminate or reduce risk

Therefore it is best to think about the hazards generated by a function from the start and to conceive of counteracting measures as early as possible. Three, in some cases four, steps are needed:

1. Eliminate the hazard if at all possible, that is, tackle the problem at its very origin.
2. If you cannot get rid of the hazard or it would be too costly, lock the hazard in (or people out).
3. If you cannot keep people's hands and feet out, monitor the presence of people near the hazard, to stop it in time.
4. Warn the users of residual risks that could not be removed or reduced satisfactorily. This is done by warning signals, signs, and notes in the operating instructions.

This process of identifying hazards, determining their risk potential and then reducing or eliminating such risks is referred to as "risk assessment". (previously also referred to as "hazard analysis"). Until the late 1980s, engineers did not normally follow a methodical approach to safety issues, but with the introduction of the Machinery Directive in 1995, "risk assessment" has become the most important step toward conformity with EU regulations.

3 Risk Assessment in Five Steps

How should you best go about risk assessment? The Machinery Directive (in Annex I, introduction) specifies five steps to be taken in risk assessment:

1. Determine the limits of the machinery, which include the intended use and any "reasonably foreseeable misuse";
2. Identify the hazards that can be generated by the machinery and the associated hazardous situations
3. Estimate the risks, taking into account the severity of the potential injury or damage to health and the probability of its occurrence
4. Evaluate the risks, with a view to determining whether risk reduction is needed
5. Eliminate the hazards or reduce the risks associated with these hazards by application of protective measures, in the order of priority set out in section 1.1.2(b) of Annex I of the Machinery Directive.

All five steps can be documented using a standard form or a software tool for risk assessment, e.g., the SafetyToolBox by pgx software solutions (download from www.axelent.de or www.pgx.de).

The entire procedure is illustrated on the next pages step by step, using a standard form. You may download the full sample from www.axelent.com. This example has been created using the SafetyToolBox software by pgx.

3.1 Step 1 – Determine Limits

In the first step, the limits of the machinery are defined. Six categories of limits with some guiding questions are provided for:

1. What is the intended use (application and its limits)?
2. In which field is the machinery to be used (private sector/industry)?
3. By whom will the machinery likely be used (professional qualifications of operators, service staff)?
4. Limits regarding space (space required, interfaces to other machinery, human-machine interface)
5. Limits regarding time (durability, pertinent service intervals for safety related parts)
6. Materials used in conjunction with the machinery (lubricants, hazardous fluids and gases)

Risk Assessment	Designation Wastes Shredder	Type Render to pieces 7
		No. 4712-5

1	**Limits of the machinery, intended use**				
1.1	Intended use	Shredding of wastes, especially of completely empty containers made of plastics, sheet metal			
1.2	Limitations of admissible use, foreseeable misuse	Do not shred: Glass, pressurised vessels (e. g. spraying cans), containers that have contained aggressive, or toxic liquids, stones, rubble, massive metal parts, explosives, tape or ribbon sha completely coiled or bundled into the shredders funnel, shavings of flammable materials (espe			
1.3	Abuse (forbidden use/applications)	Shredding of foodstuffs or animal fodder for further processing (contamination, hygienic proble Shredding of explosives and ammunition			
2	**Field of application**				
	private, consumer				
	commercial	X			
3	**User groups, endangered persons**				
3.1	Users	Index	Description	Tasks	Qualification
		3.1.1	Installation personnel	Assembly, installation	Industrial mechanic similar education Electrical installatio
		3.1.2	Maintenance staff	Maintenance, small repairs	Industrial mechanic similar education Electrical installatio
		3.1.3	Operator	Operation (use)	Orally instructed ba
3.2	Other endangered persons	Description			Cause of hazard to
4	**Space limits**				
4.1	Workplaces	Operator console on the operating and feed side. The console must be freely accessible, parti access to the emergency stop. Minimum distance to parts of a building, other machinery and ir			
4.2	Machine-power supply interface	3 Phases + N + PE for electrical power supply on the rear. Permanent wiring required for versi chines may be connected by means of a power cord with CEKON plug installed by an electrici			

Excerpt from a sample risk assessment: limits of machinery

3.2 Step 2 – Identify Risks

In the second step, many are still mainly using a list of hazards with mechanical, electrical, thermal and other types of hazards. For each hazard on the list some lines of description are added to the risk assessment. While this approach is not entirely wrong, it overlooks many hazard situations as the focus is on searching for situations matching a certain problem type ("Where, when and how can people be injured due to the mechanical hazard crushing?").

It is better to define all relevant situations along a time-line from transport to disposal (the so called "phases of the life"). Then ask: "What are the hazards incurred in that situation?". This approach was first described by Matthias Schulz in his book "Gefahrenanalyse – Warum und wie?" (Hazard Analysis – Why and How?", published in Germany in 1999 (no longer available).

The method is now referred to as "task-based risk assessment" and described in chapter 5.4 of ISO 12100; it is also recommended in the

ISO TR 14121-2. ISO 12100 requires that risk analysis be organised by "phases of life" subdivided by so called "tasks". A "task" is one of the following:

Risk assessment should be organised by phases of life and tasks because
- this is the only way to identify close to all hazardous situations and hazards
- it makes risk assessment a logic, easy-to-learn process
- the mothod saves a lot of redundant work
- the mothod conforms to current standards

a) an activity of people (operators, service staff, machine fitters …)

b) an automatic process running in the machine (a movement, or a function like pressure build-up…)

c) a combination of a and b

This approach results in straight-forward identification of hazards, because the person(s) performing the risk assessment can focus on a specific situation occurring at a specific place and time. Concerning the defined situation they will simply ask: "What could go wrong, hurting people or causing substantial damage?" An example is shown below.

Risk Assessment

Designation	Type
Wastes Shredder	Render to pieces 7
	No. 4712-5

Phase of life		Hazardous event	Measure	Directives/st
Task	Hazard			
4 Operation, operating modes				
4.1 Fill with wastes	Moving parts: crushing, cutting or severing Rotating elements: drawing in or trapping, entanglement	If the operator fills the machine while it is running, he could come in contact with the rotating knife blades and be drawn-in and injured.	Type of measure: guard, mechanical (IIa): Fixed panels on three sides (bolted to the frame). Pendulum-type flap on the filling side with interlocking, but w/out guard locking, because continued run is not relevant. See Figure 3	1.4.2.1 - Fixed 1.4.2.2 - Interlo ble guard EN ISO 12100: 6.3.2.2 EN ISO 13857: and table 2 EN ISO 14120:
			Type of measure: Combination of guards and protective devices (IIc): Monitoring of the position of the pendulum flap by means of a door safety switch. If the flap moves from its centre position, this causes immediate stop of the shredder and the feeding press mechanism.	

Excerpt from a sample risk assessment: Organised by phase of life and tasks

In this example, the operation of an industrial waste shredder has been assessed. The task is "Fill with wastes", which is done manually. The next three columns show the hazards and their causes, followed by a more detailed description of the hazard situation resulting from the task. As is seen in the example, a task may entail a number of different hazards and associated hazard situations.

3.3 Step 3 – Estimate Risk

Once the hazards have been identified, one can follow through by estimating the risk. Generally risk is the product of two factors:

- the severest direct injury from the situation (e. g. loss of fingers, hand, arm etc.)
- the probability of its occurrence (subdivided into two or three aspects, depending on the method employed)

In most cases it is fully sufficient to estimate only the severity of injury. When the injury incurred can be severe (level S2 to ISO 13849-1 or Se3/Se4 to IEC 62061) designers will inevitably have to seek a solution to eliminate or reduce the risk.

	Type Render to pieces 7	
	No. 4712-5	

	Measure	Directives/standards	Risk estimation IEC 62061							
			Se	Fr	Pr	Av	C	R	SILd	SIL
			Arguments							
	Type of measure: guard, mechanical (IIa): Fixed panels on three sides (bolted to the frame). Pendulum-type flap on the filling side with interlocking, but w/out guard locking, because continued run is not relevant. See Figure 3	1.4.2.1 - Fixed guard 1.4.2.2 - Interlocking movable guard EN ISO 12100: 2010: 6.3.2.2 EN ISO 13857: 2019: 4.2.2 and table 2 EN ISO 14120: 2015	Se4	Fr5	Pr2	Av1	8	32	SIL 2	
			Se: Severe irreversible injury, loss of body parts Fr: Frequent loading (several times per hour) Pr: It is unlikely that somebody will deliberately reach into the rotating knifes Av: The hazard is known; the operator starts machine movements by consciously pressing a start button							

Excerpt from a sample risk assessment. Risk estimation to IEC 62061

In the example shown the risk estimation includes four elements as per IEC 62061:

- severity of injury
- frequency and duration of presence in the hazard situation (exposure to the hazard)
- probability of occurrence
- ability to detect the hazard and escape timely from the hazard situation

For a detailed description of risk estimation and the methods used see Section 4 “Risk Estimation – Why and How?”, page 11.

3.4 Step 4 – Evaluate Risk

The fourth step logically follows risk estimation. It answers two questions: Can this risk be tolerated? Or is it necessary to eliminate the hazard or reduce the risk?

Risk evaluation does not mean:
- comparing the risk without safety measures to the risk after implementation of safety measures ("risk comparison")

but includes:
- determining what is state of the art
- deciding on safety measures for risk reduction so the state of the art is reached

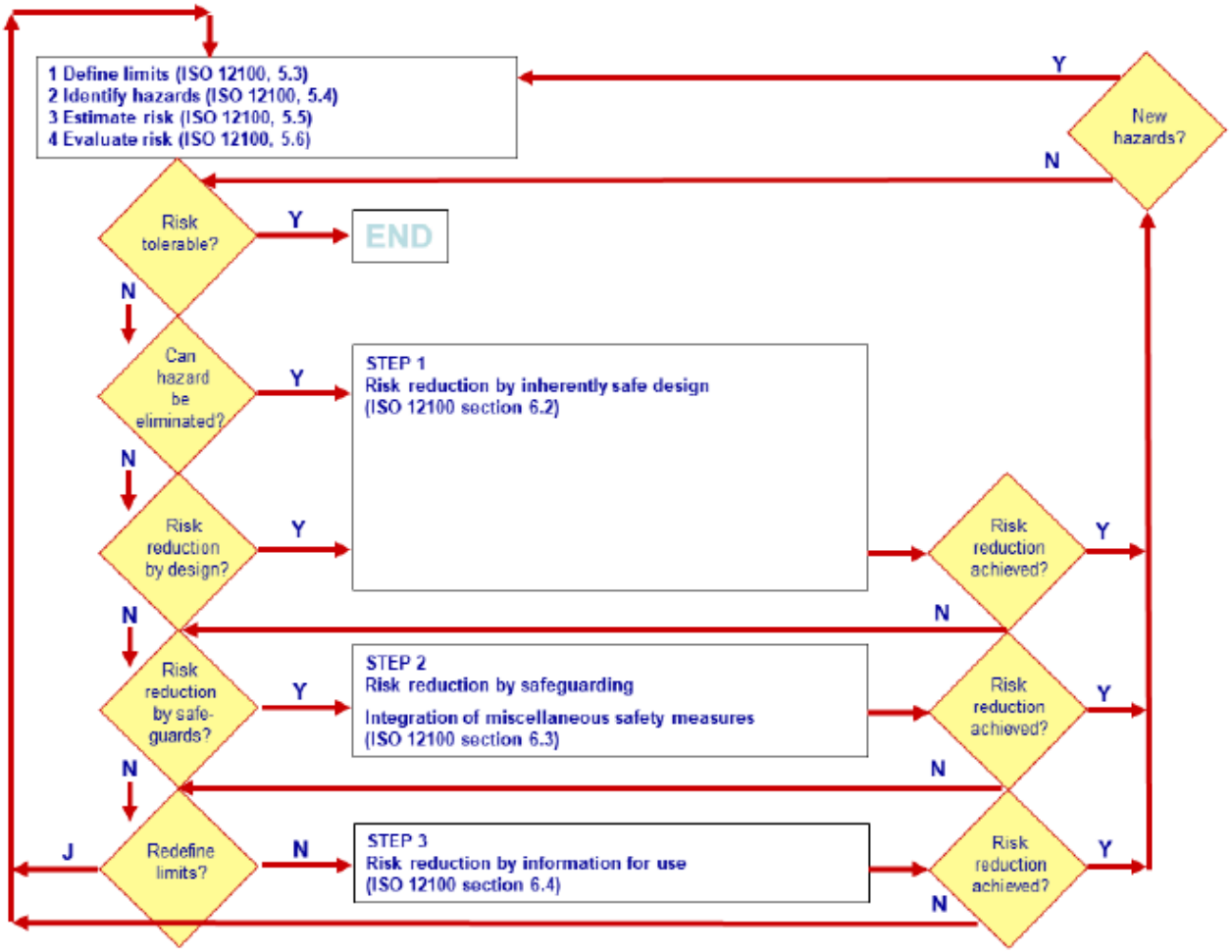
Generally speaking, severe injury always is a reason to attempt risk reduction. However, designers must seek to reduce *every* risk to the level that is allowed by the EU directives and standards. Thus, step 4 involves standards research, which in turn requires use of external tools like databases etc.

Admissible risk levels may vary from product to product. In chain saws, for instance, it is still quite normal that an operator could seriously hurt himself or others, because the revolving chain is largely uncovered. But this would not be accepted in a stationary circular saw, because covering a large part of the saw blade is possible in such machinery. The acceptability of specific risks today is largely determined by EN, EN ISO and EN IEC standards (ISO and IEC standards outside the EU).

3.5 Step 5 – Eliminate Hazard or Reduce Risk

Where risk is considered unacceptable/intolerable, the designer will choose measures to either eliminate the hazard or reduce the risk. That may include reducing the severity of the potential injuries or the probability of their occurrence. The Machinery Directive and international standards dictate taking three steps in finding adequate solutions:

- eliminate the hazard, that is, change the design so the hazard is removed (example de-burr sharp edges)
- add guards and safety-related control devices (fencing, covers, safety switches, light curtain …)
- instruct the operators and other target groups regarding residual risks and precautions to be taken (warning on the product and/or in the instructions, e.g., requirement to wear personal protective equipment like a helmet and gloves etc.)



Risk assessment – Overview of the process (adapted from ISO 12100)

4 Risk Estimation – Why and How?

The third step, risk estimation, often takes up a lot of the time spent for risk assessments. The reasons for this are:

- often excessive importance is attributed to risk estimation
- the risk elements are not defined clearly, which leads to time-consuming discussions

Risk estimation may serve three purposes:

1. Facilitating decisions on safety measures. To make such decisions, it is often sufficient to be aware of the severity of potential harm. Injury may be irreversible, such as the loss of a finger or a broken limb or hand; in such cases, risk reduction is always required. The question then only is whether it is feasible.
2. Determining the required reliability of safety-related control system functions (expressed in the form of the required PL or SIL). This is only needed if a control function is used to achieve risk reduction in a given hazard situation. The example discussed in this brochure therefore contains detailed risk estimations only for those risks that will be reduced by a function of the machine's control system.
3. Comparing risks. Generally, the risk without safety measures is compared with the risk after safety measures have been implemented. Many designers are convinced that this is mandatory and

that risk assessment is only complete if they can show that the risk has been reduced in every case. However, there are no indications to this effect in either the Machinery Directive or the applicable standards (ISO 12100, ISO 13849-1 or IEC 62061). However, it is essential to add safety measures that meet the requirements of the Machinery Directive and/or the applicable safety standards. In view of this goal, risk comparisons before/after implementation of measures are completely worthless in most cases. The time spent on such comparisons could often be used more effectively for standards research and exploration of enhanced safety measures and operating concepts. However, if you wish to do before/after risk estimations, be sure to employ a method that uses sufficiently graduated criteria, such as the method presented in Annex A of IEC 62061 or in Annex F of the US standard ANSI B11.0 (2020).

The decision for a specific method should depend on the objective of risk estimation.

Different risk estimation methods may be used. The three most well-known are:

- ISO 13849-1 Annex A – three risk elements (probability of occurrence is part of the element "Possibility of avoiding or limiting harm")
- IEC 62061 Annex A – four risk elements
- ISO TR 14121-2 section 6.3.2 – four risk elements

4.1 Risk Estimation to ISO 13849-1

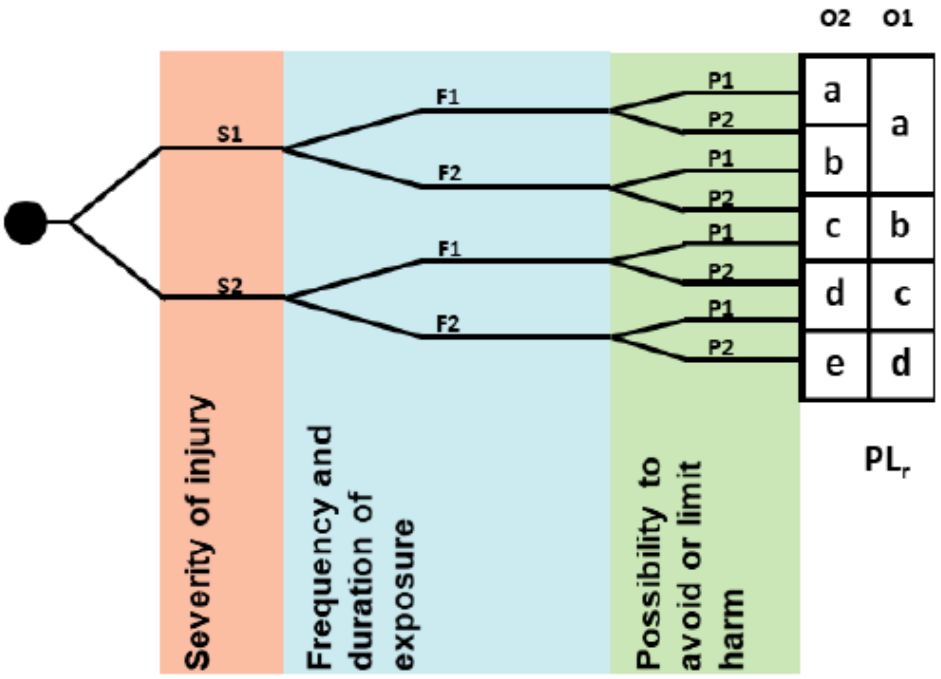
This is the most well-known but also the most problematic method. Since it has three risk elements only and a very coarse demarcation of the criteria, its results are unidimensional at best. Since 2015, the probability of occurrence can be estimated as part of the risk element "Possibility of avoiding or limiting harm". However, to use that feature, accident reports or statistical data are required to justify the estimation. The method is just good enough for its purpose: to determine the required performance level (PL_r) for safety functions.

However, ISO 13849-1 carries the so called "assumption of conformity" under the EC Machinery Directive and many think it must be preferred, therefore. However, that is no pertinent reason to decide for this method; IEC 62061 also has the assumption of conformity and its risk estimation method is thus at least equivalent.

The graph on the following page shows how the risk elements are used. Unfortunately, the definition of the criteria is very general, making it difficult to determine the limits. The table "PL/SIL" lists the interpretations of the respective results. The risk may be low to very high, and the required performance level (PL_r) ranges between a and e. It defines the required degree of reliability of a control function used to reduce a risk.

Additionally, the table shows which signal word to ISO 3864-2 should be selected for warning signs on the machine and for warning messages in the operating instructions. The three signal words Danger, Warning, and Caution represent three different risk levels.

Risk Graph



Risk graph to ISO 13849-1, supplemented by the parameter O = Probability of occurrence

Risk Elements and Criteria

Severity of harm S:

- S1 = slight injury (can be healed or is reversible)
- S2 = serious/fatal injury (cannot be healed or is irreversible; generally this begins with broken limbs, since this often results in permanent limitations for the person injured)

Frequency and/or duration of exposure F:

- F1 = seldom to quite often and/or short exposure time
- F2 = frequent to continuous
  (Limit > 4/hour to EN ISO 13849-1 and total exposure time > 1/20 of operating time)

Possibility of avoiding or limiting the harm P:

- P1 = possible under specific conditions
- P2 = nearly impossible

Three questions should be asked concerning the risk element P:

- Is the hazard detectable or known due to training?
- When the hazard occurs and is detected by the person, can he/she still escape/react, especially considering the speed of motion or the time remaining until he/she is injured?
- Does the person him-/herself trigger the hazard
  (e. g., by consciously causing start by operating a control)?

Probability of occurrence O

- O1 = Low (evidenced by statistic data or a documented accident history)
- O2 = High or probability cannot be estimated

PL/SIL

PL ISO 13849-1	SIL IEC 62061	Risk	Recommended signal word to IEC/IEEE 82079-1 ISO 3864-2
PL "a"	OM	low risk	CAUTION
PL "b"*	SIL1	moderate risk	CAUTION
PL "c"		medium risk	WARNING
PL "d"	SIL2	high risk	WARNING, DANGER
PL "e"	SIL3	very high risk	DANGER

* PL b does not correspond to SIL1 if the control category is only B

4.2 Risk Estimation to IEC 62061

This is the best-documented method. Since it includes all four risk elements and uses finely graduated criteria, it is the most precise and also suitable for risk comparisons.

We recommend using IEC 62061, because:
- it uses all four risk elements, which are finely graduated
- the results can be interpreted as a PL directly
- the method is universally applicable for risk comparisons

IEC 62061 carries the assumption of conformity under the EC Machinery Directive just like ISO 13849-1, however, since 2005 already. The method therefore is completely equivalent to ISO 13849-1. Additionally, its results are transferable, that is, the PL can be found with it just as it can with ISO 13849-1.

Risk Table

Severity of injury Se	Class C (Fr+Pr+Av)				
	3-4	5-7	8-10	11-13	14-15
4	SIL 2	SIL 2	SIL 2	SIL 3	SIL 3
3	OM	OM	SIL 1	SIL2	SIL 3
2	OM	OM	OM	SIL 1	SIL 2
1	OM	OM	OM	OM	SIL 1

OM = other measure recommended, that is, there are no requirements concerning the reliability in IEC 62061. Allocation of SIL 1 to PL b or c (compare IEC 62061:2021 Annex A):

- Se4 + C4 = PL b, S4 + K4 = PL c
- Se3 + C8 = PL b, S3 + C9-10 = PL c
- Se2 + C11 = PL b, Se2 + C12-13 = PL c
- Se1 + C14 = PL b, Se1 + C15 = PL c

Risk Elements and Criteria

Severity of injury Se:

1	reversible: requiring first aid
2	reversible: requiring attention from a medical practitioner
3	irreversible: broken limb(s), losing a finger(s)
4	irreversible: death, losing an eye or arm

Frequency and duration of exposure to hazard Fr:

2	< 1 per year
3	< 1 per 2 week to ≥ 1 per year
4	< 1 per day to ≥ 1 per 2 weeks
5	< 1 per hour to ≥ 1 per day
5	≥ 1 per hour

If the duration of the exposure is < 10 minutes, the value may be reduced by one. However, this does not apply if the frequency of exposure is ≥ 1 per hour.

Probability of occurrence Pr:

1	negligible
2	rarely
3	possible
4	likely
5	very high

The following questions should be asked:

- Is the personnel under stress while doing their work/in the situation (e. g., by a piece-rate, time constraints)?
- Is the person well trained and familiar with the risks?
- Is spontaneous failure of components (not of the safety-related control system) or triggering of malfunctions likely?

Take the mean value from the estimation of these questions.

Probability of avoiding or limiting harm Av:

1	probable
3	rarely
5	impossible

Three questions should be asked concerning the risk element Av:

- Is the hazard detectable or known due to training?
- Can the person still escape/react, especially considering the speed of motion?
- Does the person him-/herself trigger the hazard (e. g., by consciously causing start by operating a control)?

SIL/PL

SIL IEC 62061	PL ISO 13849-1	Risk	Recommended signal word to IEC/IEEE 82079-1 ISO 3864-2
OM	PL "a"	low risk	CAUTION
SIL1	PL "b"*	moderate risk	CAUTION
	PL "c"	medium risk	WARNING
SIL2	PL "d"	high risk	WARNING, DANGER
SIL3	PL "e"	very high risk	DANGER

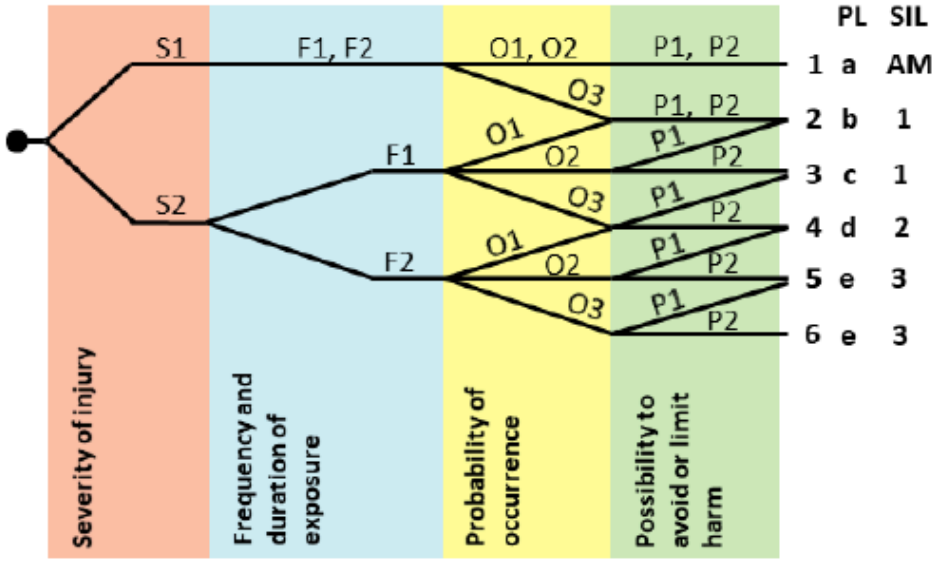
* PL b does not correspond to SIL1 if the control category is only B

4.3 Risk Estimation to ISO TR 14121-2

ISO TR 14121-2 is not a standard in the true sense of the meaning but a technical report (TR) authored by an ISO work group. This report is a summary of different methods practised in the industry.

The method for risk estimation presented in section 6.3.2 is gaining popularity. The reason for this is that it includes the fourth risk element – the probability of occurrence. But otherwise the method has the same weaknesses as does ISO 13849-1 Annex A. Even worse: The criteria for the probability of occurrence can hardly be used, especially for new products, because they depend on data from application of the machine.

Risk Graph



Risk graph to ISO TR 14121-2, 6.3.2 (Allocation of PL/SIL by author)

Risk Elements and Criteria

Severity of injury S:

- S1 *slight injury*, usually reversible; examples: scratch, laceration, bruise, light wound requiring first aid; the person is not more than two days incapable of performing the same task
- S2 *serious injury*, usually irreversible, including fatality; examples: broken or torn-out or crushed limb, fracture, serious injury requiring stitches, major musculoskeletal trauma (MST) etc.; the person is more than two days incapable of performing the same task

Frequency and/or duration of exposure to hazard F:

- F1 *seldom to quite often and/or short duration of exposure*
  Exposition twice or less per work shift or less than 15 min cumulated exposure per work shift
- F2 *frequent to continuous and/or long duration of exposure*
  Exposition more than twice per work shift or more than 15 min cumulated exposure per work shift

Probability of occurrence of a hazardous event O:

- O1 *low*, so unlikely that it can be assumed that occurrence may not be experienced
- O2 *medium*, likely to occur sometime, technical failure observed in the two last years. Inappropriate human action by a well-trained person aware of the risk and having more than six months experience on the work station.
- O3 *high*, likely to occur frequently, technical failure regularly observed (every six months or less). Inappropriate human action by an untrained person having less than six months experience on the work station.

Possibility of avoidance or reduction of harm A:

- A1 *possible under some conditions:*, if parts move at a speed less than 250 mm/s and the exposed worker is familiar with the risk and with the indication of a hazardous situation or impending event; the worker also has to be capable of noticing the hazardous situation and being capable of reacting. Avoidance is possible depending on particular conditions (temperature, noise, ergonomic, etc.). *The person at risk himself triggers the hazardous event (presses a start button or enabling button) – the latter has been added by the author, it is not contained in the standard.*
- A2 *impossible*

SIL/PL

Originally, the method was not meant to be used to determine the PL or SIL, however, it may also be used for this purpose. The graph above shows a possible allocation of the results to the PL/SIL and the signal words for warning signs and messages (added by the author).