A Practical Approach to Risk Assessment and Risk Reduction

Presented by
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Today's Learning Objectives

- What is a risk assessment and why do I have to do it?
- Who can do a risk assessment?
- How do I do it?
- What is the difference between risk assessment and risk reduction?
- What tools are available?

What is it?

- Risk Assessment
  - The process by which the intended use (and reasonably foreseeable misuse) of the machine, the tasks and hazards, and the level of risk are determined

- Risk Reduction
  - The application of protective measures to reduce the risk to a tolerable level

Why do it?

- To create a safer working environment for employees (as required by OSHA)
- To reduce costs
- To comply with national and international consensus standards, including:

ANSI B11.0-2010 – Safety of Machinery – General Requirements and Risk Assessment

ANSI B11.TR3-2000 – Risk Assessment and Risk Reduction – A Guide to Estimate, Evaluate and Reduce Risks Associated with Machine Tools

ANSI/RIA R15.06-1999 (R2009) – For Industrial Robots and Robot Systems – Safety Requirements

NFPA 79-2012 – Electrical Standard for Industrial Machinery

ANSI/ASSE Z244.1-2003 (R2008) – Control of Hazardous Energy – Lockout/Tagout and Alternative Methods

ANSI/PMMI B155.1-2011 – Standard for Packaging Machinery and Packaging-Related Converting Machinery – Safety Requirements for Construction, Care, and Use

SEMI S10-0307 – Safety Guideline for Risk Assessment and Risk Evaluation Process

MIL-STD-882D-2000 – Standard Practice for System Safety

CSA Z432-04 – Safeguarding of Machinery – Occupational Health and Safety

CSA Z434-03 – Industrial Robots and Robot Systems – General Safety Requirements

CSA Z460-05 – Control of Hazardous Energy – Lockout and Other Methods

NOM-004-STPS-1999 – Protection Systems and Safety Devices for Machinery and Equipment Used in the Workplace

ISO 12100:2010 – Safety of machinery – General principles for design – Risk assessment and risk reduction

EN 954-1:2000 / ISO 13849-1:1999 – Safety of machinery – Safety-related parts of control systems – Part 1: General principles of design

ISO 13849-1:2006 – Safety of machinery – Safety-related parts of control systems – Part 1: General principles of design

2006/42/EC – European Machinery Directive

How do I do it?

- Regardless of which standard you follow, the process contains 12 essential steps
- You can create your own process, as long as it's based on industry best practices
- You can conduct the process in house, request it from your OEM, or contract an outside service provider

Identify Machine / Process

- Usually done in reaction to an accident / near miss that has already occurred
- Think Proactive!
- Can be prioritized based on common sense (more hazardous machines first)
  - Based on hazards and/or frequency of use

Collect Proper Information

- Limits of the machine
- Requirements for the lifecycle of the machine
- Design drawings, sketches, system descriptions, or other means of establishing the nature of the machine
- Information concerning energy sources
- Any accident and incident history
- Any information about damage to health
- System layout and proposed building / existing system(s) integration
- Affected personnel
- Level of training, experience, or ability of all personnel
- Exposure of other persons to the hazards associated with the machine where it can be reasonably foreseen

Gather Proper Personnel

EHS manager

Operators

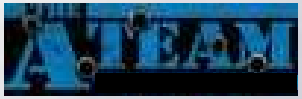
Maintenance personnel

Engineers

Electricians

Production managers

Specialists

Use 

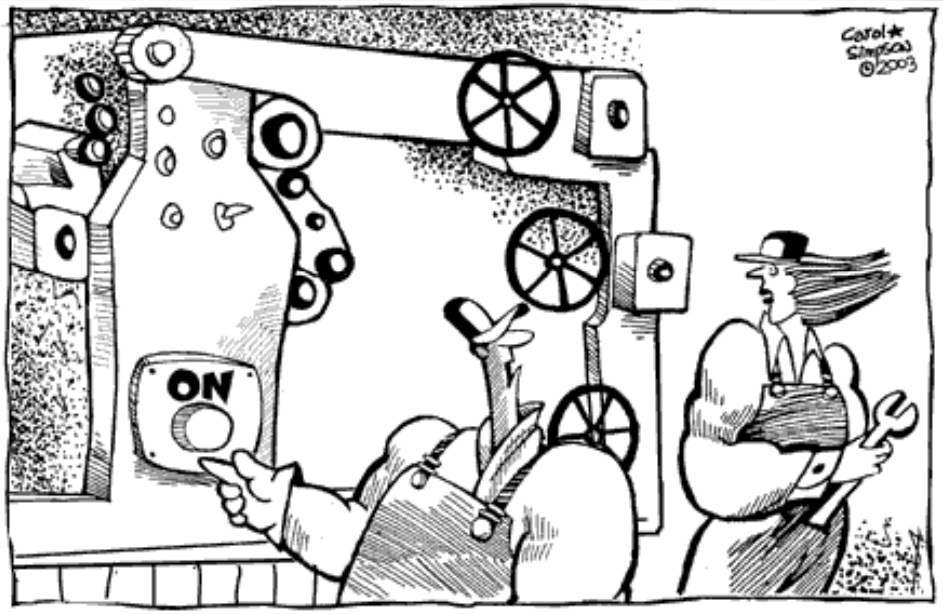
approach

Observe Machine in Use

Although many machines are similar in design, they are adapted to perform specific or different operations

The best way to understand the operation and maintenance of a machine is to see it in use

- This helps ensure safety and compliance while understanding and meeting productivity needs



"This machine is perfectly safe...
As long as you never press this button."

Identify Hazardous Areas

- Follow task/hazard approach

- Tasks include:

Packing and transporting
Unloading/unpacking
Systems installation
Start up/commissioning
Set up and try out
Operation (all modes)
Tool change
Major repair

Planned maintenance
Unplanned maintenance
Recovery from crash
Troubleshooting
Housekeeping
Decommissioning
Disposal

Task / Hazard Approach

Personnel	Task	Hazard
Operator		
Maintenance		
Trainees		
Passers-by		
Managers		
Supervisors		
Programmers		
Engineers		
Office Personnel		
Quality Coach		
Sales Personnel		
Contractors		
Riggers		

Task / Hazard Approach

Personnel	Task	Hazard
Operator	Load	
Operator	Unload Part	
Operator	Unload Scrap	
Operator	Cycle	
Operator	Lube Die	
Operator	Clean Die	
Operator	Tape Die	
Operator	Power Up	
Operator	Power Down	
Operator	Clean Press	
Operator	Clean Workspace	
Operator	Teach Trainees	
Maintenance	Change Die	
Maintenance	First Piece Verification	
Maintenance	Preventative Maintenance	
Maintenance	Recovery from Crash	

Task / Hazard Approach

Personnel	Task	Hazard
Operator	Load	Shearing
Operator	Load	Cutting or Severing
Operator	Load	Stabbing or Puncturing
Operator	Load	Contact with Live Parts
Operator	Load	Reaction to Stainless Steel
Operator	Load	Failure of the Control System
Operator	Load	Failure of the Equipment
Operator	Load	Slip, Trip, or Fall
Operator	Load	Falling Objects
Operator	Load	Ejected Objects or Fluids
Operator	Unload Part	Crushing
Operator	Unload Part	Shearing
Operator	Unload Part	Cutting or Severing
Operator	Unload Part	Contact with Live Parts
Operator	Unload Part	Reaction to Stainless Steel
Operator	Unload Part	Failure of the Control System

Identifying Tasks & Hazards

- ANSI B11.0-2010

  Identifying tasks and hazards is a critically important part of the risk assessment process because hazards not identified can create substantial unknown risks. There are many different approaches to identifying hazards. Depending on the complexity of the machinery, useful methods may include but are not limited to:

  - using intuitive operational and engineering judgment;
  - examining system specifications and expectations;
  - reviewing codes, regulations, and consensus standards;
  - interviewing current or intended system users and/or operators;
  - consulting checklists;
  - reviewing studies from other similar systems;
  - evaluating the potential for unwanted energy releases/exposures to hazardous environments;
  - reviewing historical data/industry experience, incident investigation reports (including accident or near-miss events), OSHA, Bureau of Labor Statistics and National Safety Council data, manufacturer's literature;
  - considering potential mishaps with surrounding equipment and operations;
  - brainstorming.

Assumptions

- The risk assessment process includes identifying hazards regardless of the existence of risk reduction (safeguarding) measures.
- The machine should not be considered harmless as shipped and guarded.
- To assure that all hazards are included, hazard identification should be conducted with all safeguards conceptually removed.
  - This is to assure that hazards are not ignored due to an assumption that the safeguard supplied is adequate for all tasks, including reasonably foreseeable misuse.
- Existing safeguards that help meet the risk reduction objectives can be retained after evaluating their performance.
  - This decision will be confirmed during the validation/verification portion of the risk assessment.

Identify the Risk Level and Required Level of Risk Reduction

- There are several recognized methods to identify (label) risk levels
  - ANSI, RIA, CSA, EN, ISO
- Choose the method which is easiest and most practical to apply at your location
- Risks must be aligned to a risk reduction category that incorporates the selection of safeguarding devices and safety-related parts of the control system

ANSI B11.TR3

- 7.2 Severity of harm
- Severity of harm addresses the degree of injury or illness that could occur. The degrees are based on extent of injury or illness (from death to no injury), and extent of treatment involved. The following is an example of severity levels:
  - **Catastrophic** – death or permanently disabling injury or illness (unable to return to work)
  - **Serious** – severe debilitating injury or illness (able to return to work at some point)
  - **Moderate** – significant injury or illness requiring more than first aid (able to return to same job)
  - **Minor** – no injury or slight injury requiring no more than first aid (little or no lost work time)

    When determining risk, the worst credible severity of harm is to be selected.

- 7.3 Probability of occurrence of harm
- Probability of occurrence of harm is estimated by taking into account the frequency, duration and extent of exposure, training and awareness, and the presentation of the hazard. The following is an example of probability levels:
  - **Very likely** – near certain to occur
  - **Likely** – may occur
  - **Unlikely** – not likely to occur
  - **Remote** – so unlikely as to be near zero

    When estimating probability, the highest credible level of probability is to be selected.

ANSI B11.TR3

Probability	Severity Level			
	Catastrophic	Serious	Moderate	Minor
Very Likely	High	High	High	Medium
Likely	High	High	Medium	Low
Unlikely	Medium	Medium	Low	Negligible
Remote	Low	Low	Negligible	Negligible

Table 1: Risk Determination Matrix

ANSI B11.TR3

- Safeguards providing the *highest* degree of risk reduction are:
  - **Barrier guard or protective device preventing intentional exposure** of any part of the body to the hazard, and secured with special fasteners or a lock. If moveable, such a barrier should be interlocked using system control criteria as defined in this paragraph.
  - **Control systems** having **redundancy with continuous self-checking** to ensure the continuance of performance.
- Safeguards providing *high / intermediate* risk reduction are:
  - **Barrier guard or protective device preventing unintended exposure** of any part of the body to the hazard, and not removable or adjustable by unauthorized persons. If moveable, such a barrier should be interlocked using system control criteria as defined in this paragraph.
  - Physical devices that do not require adjustment for use or other operator intervention.
  - – **Control systems** having **redundancy with self-checking** upon startup to ensure the continuance of performance.
- Safeguards providing *low / intermediate* risk reduction are:
  - **Barrier guard or protective device providing simple guarding against inadvertent exposure** to the hazard. Examples are a fixed screen, chuck guard, or moveable barrier with simple interlocking using system control criteria as defined in this paragraph.
  - Physical devices that require adjustment for use.
  - **Control systems** (including associated protective devices, actuators and interfaces) having **redundancy** that may be manually checked to ensure the continuance of performance.
- Safeguards providing the *lowest* degree of risk reduction are:
  - **Physical barrier providing tactile or visual awareness of the hazard**, or minimal protection against inadvertent exposure. Examples are post and rope, swing-away shield, or moveable screen.
  - Electrical, electronic, hydraulic or pneumatic devices and associated **control systems** using a **single-channel** configuration.

ANSI/RIA R15.06

Table 1

Factor	Category		Criteria
Severity	S2	Serious Injury	Normally Irreversible; or fatality; or requires more than first-aid as defined in OSHA 1904.12
	S1	Slight Injury	Normally reversible; or requires only first-aid as defined in OSHA 1904.12
Exposure	E2	Frequent Exposure	Typically exposure to the hazard more than once per hour.
	E1	Infrequent Exposure	Typically exposure to the hazard less than once per day or shift.
Avoidance	A2	Not Likely	Cannot move out of the way; or inadequate reaction time; or robot speed greater than 250mm/sec.
	A1	Likely	Can move out of the way; or sufficient warning/reaction time; or robot speed less than 250mm/sec.

Table 1 - Hazard Severity/Exposure/Avoidance Categories

ANSI/RIA R15.06

Table 2

Severity of Exposure	Exposure	Avoidance	Risk Reduction Category
S2 Serious Injury More than First-aid	**E2** Frequent Exposure	**A2** Not Likely	**R1**
		A1 Likely	**R2A**
	E1 Infrequent Exposure	**A2** Not Likely	**R2B**
		A1 Likely	**R2B**
S1 Slight Injury First-aid	**E2** Frequent Exposure	**A2** Not Likely	**R2C**
		A1 Likely	**R3A**
	E1 Infrequent Exposure	**A2** Not Likely	**R3B**
		A1 Likely	**R4**

Table 2 - Risk reduction decision matrix prior to safeguard selection

ANSI/RIA R15.06

Table 3

Category	SafeGuard Performance	Circuit Performance
R1	Hazard Elimination or hazard substitution (9.5.1)	Control Reliable (4.5.4)
R2A	Engineering controls preventing acess to the hazard, or stopping the hazard (9.5.2), e.g. interlocked barrier guards, light curtains, safety mats, or other presence sensing devices (10.4)	Control Reliable (4.5.4)
R2B		Single Channel with monitoring (4.5.3)
R2C		Single Channel (4.5.2)
R3A	Non interlocked barriers, clearance, procedures and equipment (9.5.3)	Single Channel (4.5.2)
R3B		Simple (4.5.1)
R4	Awareness means (9.5.4)	Simple (4.5.1)

Table 3 - Safeguard Selection Matrix

Risk Reduction Measures

Modified Table 3

Risk reduction Index	Safeguard Performance	Circuit Performance			
		ANSI/RIA R15.06-1999 (R2009)	ISO 10218-1	ISO 10218-2	
			ISO 13849-1:1999	ISO 13849-1:2006	IEC 62061:2005
			Category	PL	SIL
R1	Hazard Elimination or hazard substitution	Control Reliable	(4) 3	(e) d	(3) 2
R2A	Engineering controls preventing acess to the hazard, or stopping the hazard, e.g. interlocked barrier guards, light curtains, safety mats, or other presence sensing devices	Control Reliable	3	d	2
R2B		Single Channel with Monitoring	2	d / c	2 / 1
R2C		Single Channel	1	c	1
R3A	Non interlocked barriers, clearance, procedures and equipment	Single Channel	1	b	1
R3B		Simple	b	b	1
R4	Awareness means	Simple	b	a	n/a

Table 3 - Safeguard Selection Matrix

ANSI/RIA R15.06

- R1 Risk reduction shall be accomplished by hazard elimination or hazard substitution which does not create an equal or greater hazard. When hazard elimination or substitution is not possible, all provisions of a category R2 risk reduction shall apply and provisions of categories R3 and R4 shall be provided for safeguarding residual risk.

- R2 Safeguarding shall be by means that prevent access to the hazard, or cause the hazard to cease. Provisions of categories R3 and R4 may be used for safeguarding residual risk.

- R3 Safeguarding, at a minimum, shall be by means of non-interlocked barriers, clearance from the hazard, written procedures, and personal protective equipment if applicable. Provisions of Category R4 may also be used for safeguarding residual risk.

- R4 Safeguarding, at a minimum, shall be by administrative means, awareness means including audio/visual warnings and training.

EN 1050 / ISO 14121

S: Severity of Potential injury

- **S1**: Slight injury(minor cuts or bruises, requires first-aid)
- **S2**: Severe injury(broken bone, loss of limb or death)

F: Frequency of exposure to potential hazard

- **F1**: Infrequent exposure
- **F2**: Frequent to continuous exposure

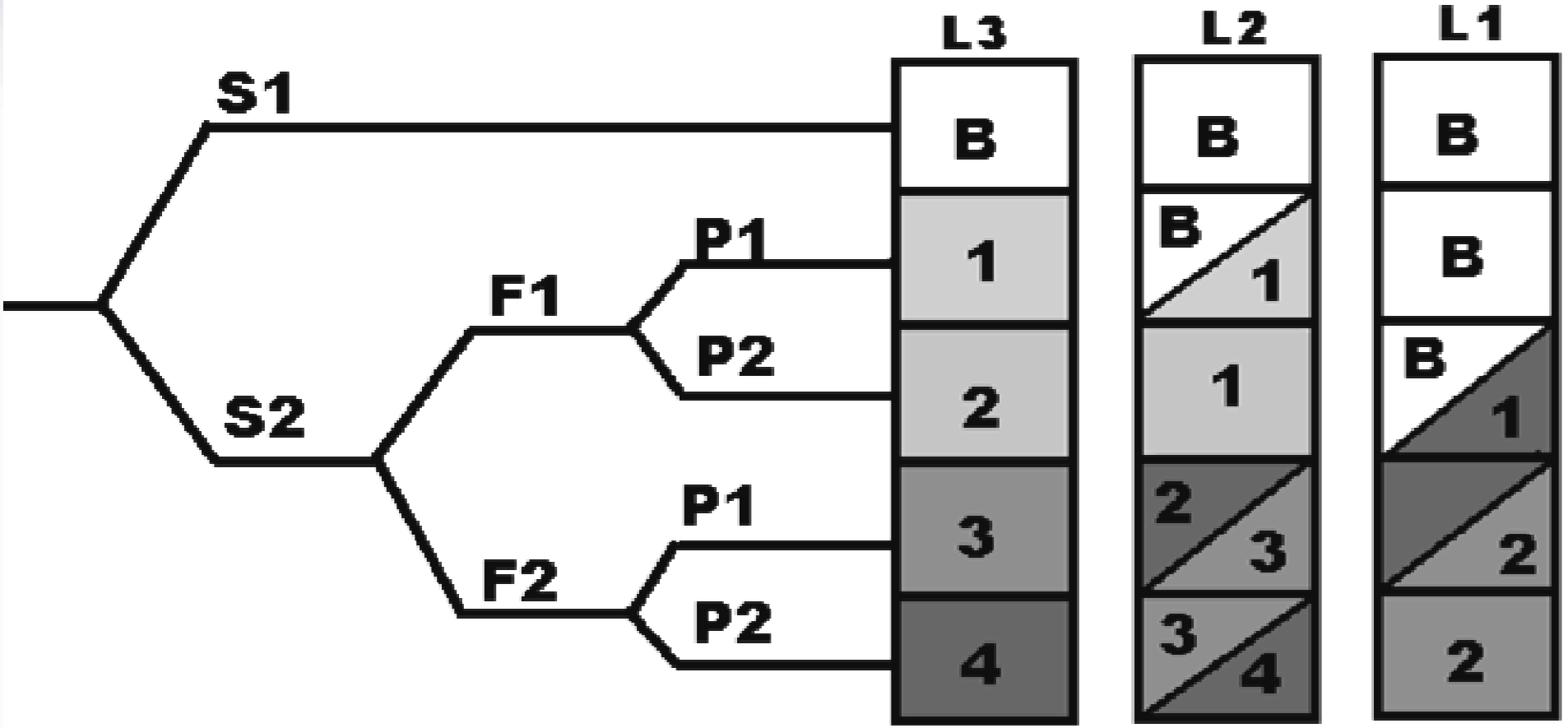
P: Possibility of avoiding the hazard as it occurs (generally related to the speed / frequency of movement of the hazard and distance to the hazard point)

- **P1**: Possible
- **P2**: Less possible

L: Likelihood of occurrence (in event of a failure)

- **L1**: Very likely
- **L2**: Unlikely
- **L3**: Highly unlikely

EN 1050 / ISO 14121



EN 954-1:1996 / ISO 13849-1:1999

Category	Summary of requirements	System behaviour	Principles to achieve safety
B (see 6.2.1)	Safety-related parts of control systems and/or their protective equipment, as well as their components, shall be designed, constructed, selected, assembled and combined in accordance with relevant standards so that they can withstand the expected influence.	The occurrence of a fault can lead to the loss of the safety function.	Mainly characterized by selection of components
1 (see 6.2.2)	Requirements of B shall apply. **Well-tried components and well-tried safety principles** shall be used.	The occurrence of a fault can lead to loss of the safety function, but the probability of occurrence is lower than for category B.	
2 (see 6.2.3)	Requirements of B and the use of well-tried safety principles shall apply. Safety function shall be checked at suitable intervals by the machine control system.	- The occurrence of a fault can lead to loss of the safety function between checks. - The loss of safety function is detected with the check.	Mainly characterized by structure
3 (see 6.2.4)	Requirements of B and the use of well-tried safety principles shall apply. Safety-related parts shall be designed so that: - **a single fault in any of these parts does not lead to loss of the safety function**, and - whenever reasonably practicable the single fault is detected.	- When a single fault occurs, the safety function is always performed. - Some but not all faults will be detected. - Accumulation of undetected faults can lead to loss of the safety function.	
4 (see 6.2.5)	Requirements of B and the use of well-tried safety principles shall apply. Safety-related parts shall be designed so that: - a single fault in any of these parts does not lead to loss of the safety function, and - **the single fault is detected at or before the next demand upon the safety function**. If this is not possible, then an accumulation of faults shall not lead to a loss of the safety function.	- When the faults occur the safety function is always performed. - The faults will be detected in time to prevent loss of the safety function.	

Table 2 – Summary of requirements for categories

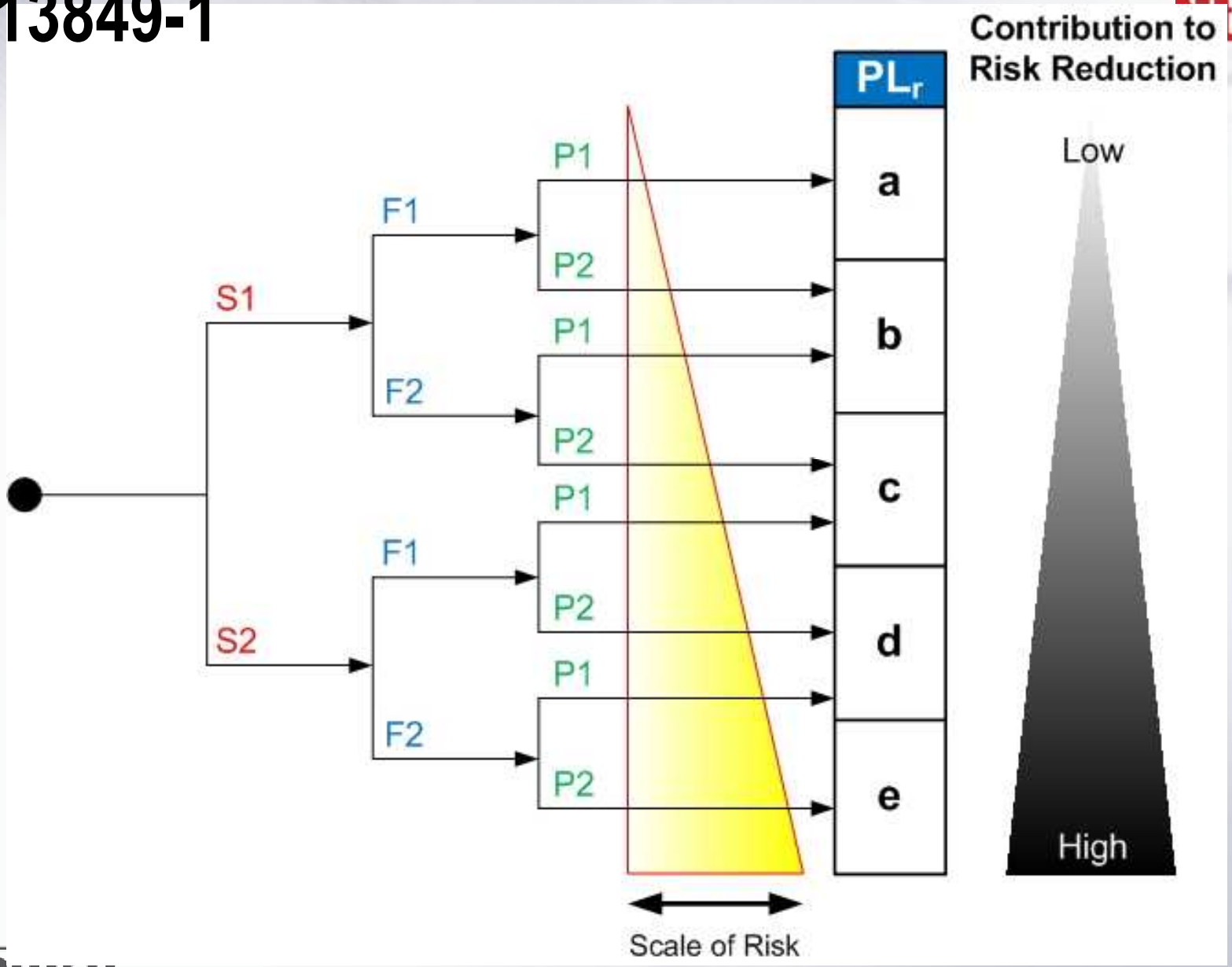
(for full requirements see clause 6)

SYSMAC always in control

ISO 13849-1

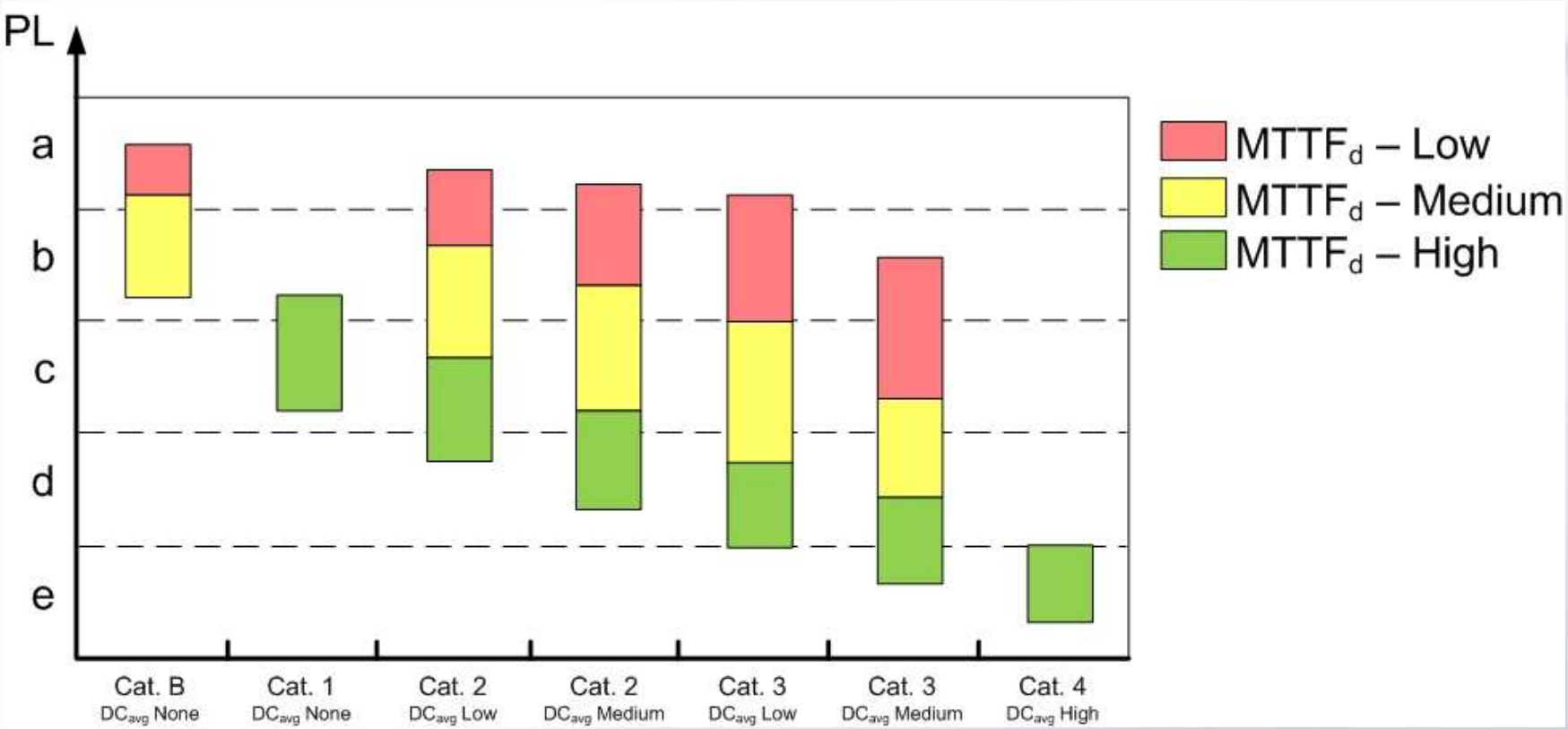
RISK FACTOR	VALUE	DEFINITION
Severity of Injury	S1	Slight (normally reversible injury)
	S2	Serious (normally irreversible injury or death)
Frequency and/or Exposure to Hazard	F1	Seldom to less-often and/or exposure time is short
	F2	Frequent to continuous and/or exposure time is long
Possibility of Avoiding Hazard of Limiting Harm	P1	Possible under specific conditions
	P2	Scarcely possible

ISO 13849-1

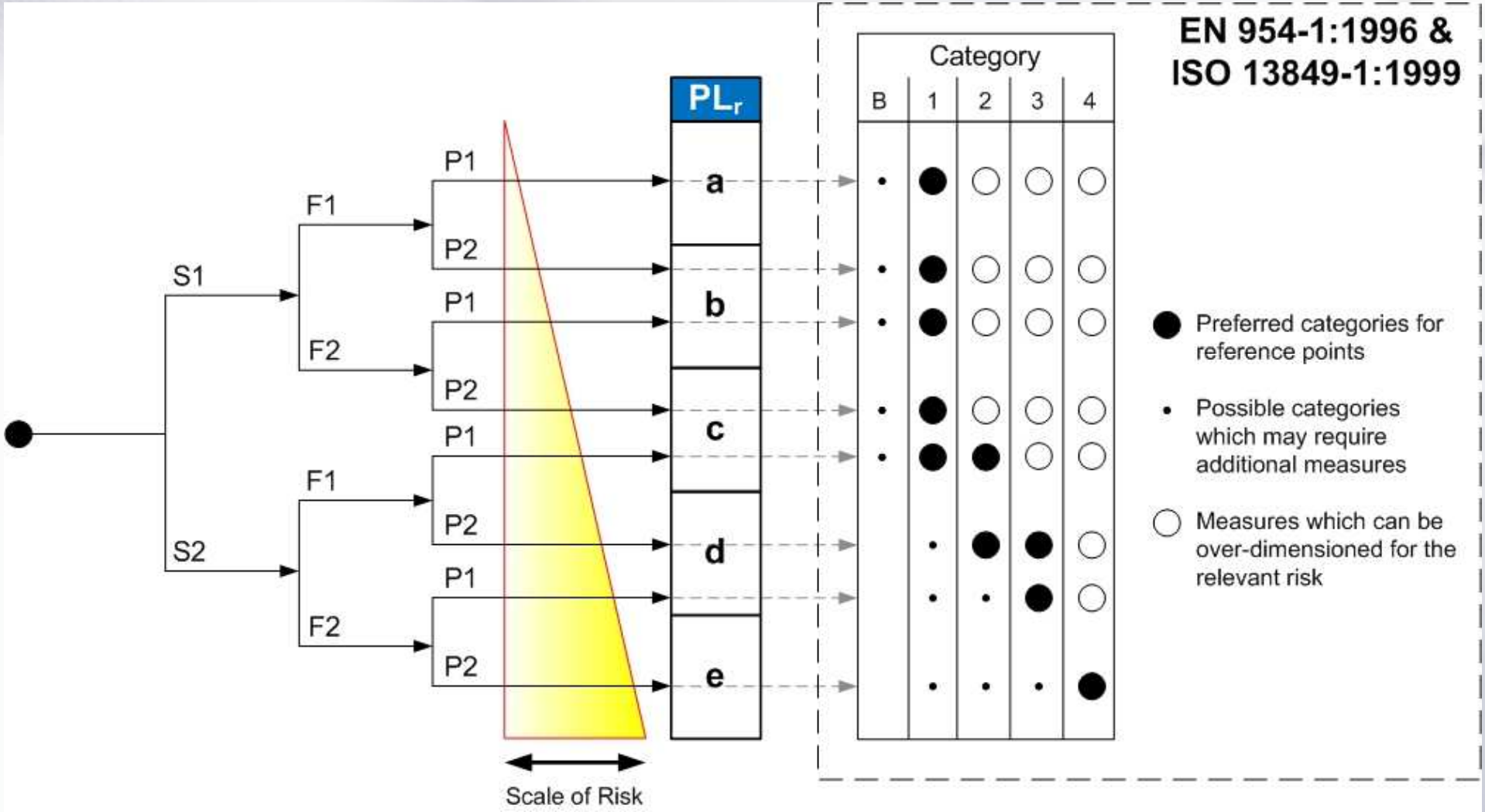


ISO 13849-1

Relationship between Categories, DC_{avg}, and $MTTF_d$ of Each Channel and PL



EN 954-1 vs. ISO 13849-1

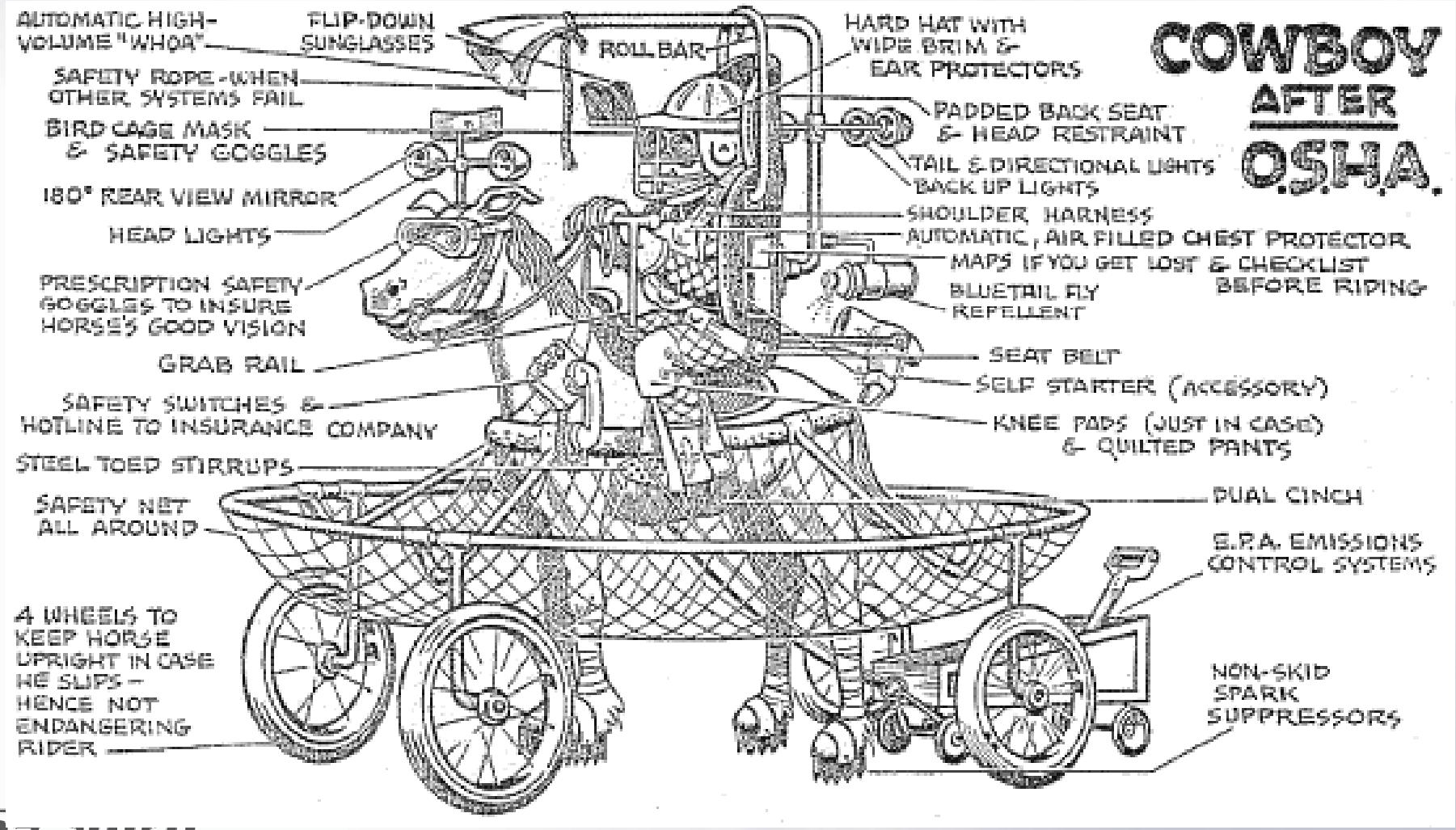


Comparison of Circuit Performance Requirements

CIRCUIT PERFORMANCE REQUIREMENTS						
ANSI B11.TR3-2000 ANSI/ASSE Z244.1-2003 (R2008)		ANSI/RIA R15.06-1999 (R2009) CSA Z432-04 & Z434-03		ISO 10218-1:2007 ISO 13849-1:1999 (EN 954-1:1996)	ISO 10218:20(11?) ISO 13849-1:2006	 IEC 62061:2005
Index	Circuit Performance	Index	Circuit Performance	Category	PL	SIL
High	Redundancy with Continuous Self-Checking	R1	Control Reliable	(4) 3	(e) d	(3) 2
High	Redundancy with Continuous Self-Checking	R2A	Control Reliable	3	d	2
No Equivalent						
		No Equivalent		*No Equivalent*	*No Equivalent*	*No Equivalent*
		No Equivalent		*No Equivalent*	*No Equivalent*	*No Equivalent*
No Equivalent						
No Equivalent						

While there are similarities between the levels of risk reduction in the various columns, an exact one-to-one comparison is virtually impossible. This chart is intended to show the comparative similarities between each standard. Where risk reduction measures depend on configurable devices, the reliability of these devices and the system should be appropriate for the level of risk.

Selecting Protective Measures Commensurate with Risk Level



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Create Appropriate Risk Reduction System

- Follow hierarchy of control
  - Elimination / substitution of the hazard
  - Engineering controls
    - Safeguarding devices (interlock switches, light curtains, safety mats, etc.)
    - Electrical / pneumatic / hydraulic circuits
  - Awareness means (lights, signs, signals, etc.)
  - Training and procedures (administrative controls)
  - Personal protective equipment (PPE)

Hierarchy of Control

Most Effective

Least Effective

PROTECTIVE MEASURE	EXAMPLES	INFLUENCE ON RISK FACTORS	CLASSIFICATION
Elimination **or** **Substitution**	➢ Eliminate the need for human interaction in the process ➢ Eliminate pinch points (increase clearance) ➢ Automated material handling (robots, conveyors, etc.)	➢Impact on overall risk (elimination) by affecting severity and probability of harm ➢May affect severity of harm, frequency of exposure to the hazard under consideration, and/or the possibility of of avoiding or limiting harm depending on which method of substitution is applied.	**Design Out**
Safeguarding Technologies / Protective Devices	➢ Barriers ➢ Interlocks ➢ Presence sensing devices (light curtains, safety mats, area scanners, etc.) ➢ Two hand control and two hand trip devices	➢Greatest impact on the probability of harm (occurrence of hazardous events under certain circumstances) ➢Minimal if any impact on severity of harm	**Engineering Controls**
Awareness Means	➢ Lights, beacons, and strobes ➢ Computer warnings ➢ Signs and labels ➢ Beepers, horns, and sirens	➢Potential impact on the probability of harm (avoidance) ➢No impact on severity of harm	**Administrative Controls**
Training and Procedures	➢ Safe work procedures ➢ Safety equipment inspections ➢ Training ➢ Lockout / Tagout / Tryout	➢Potential impact on the probability of harm (avoidance and/or exposure) ➢No impact on severity of harm	
Personal Protective Equipment (PPE)	➢ Safety glasses and face shields ➢ Ear plugs ➢ Gloves ➢ Protective footwear ➢ Respirators	➢Potential impact on the probabilty of harm (avoidance) ➢No impact on severity of harm	

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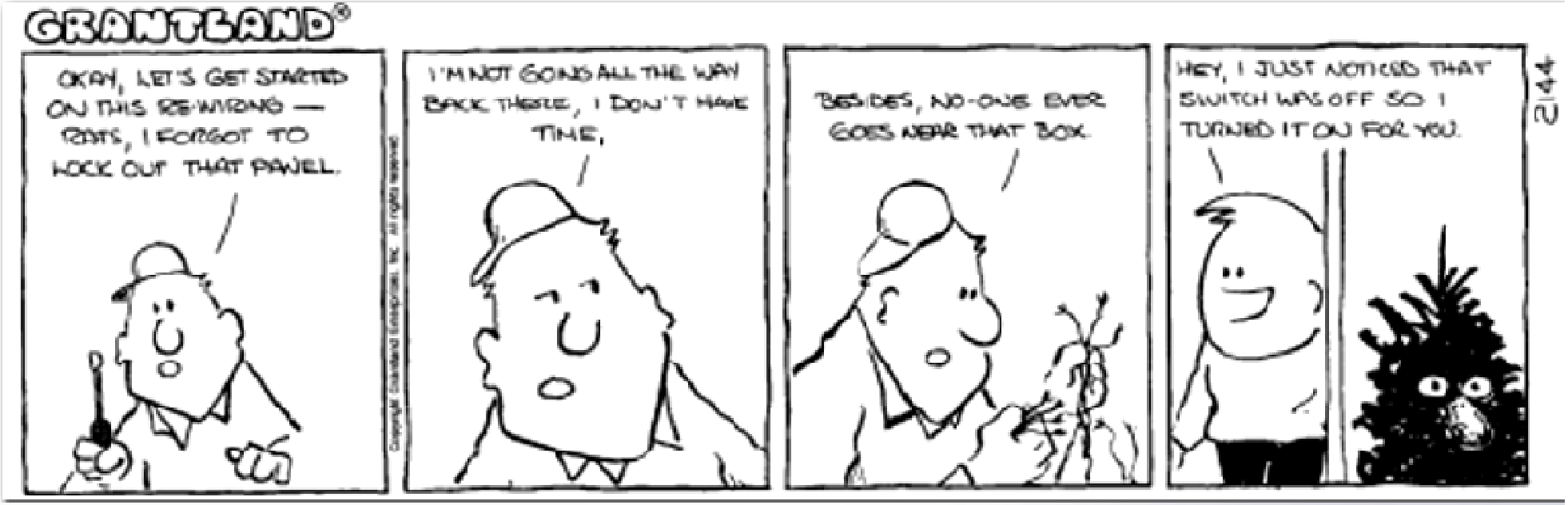
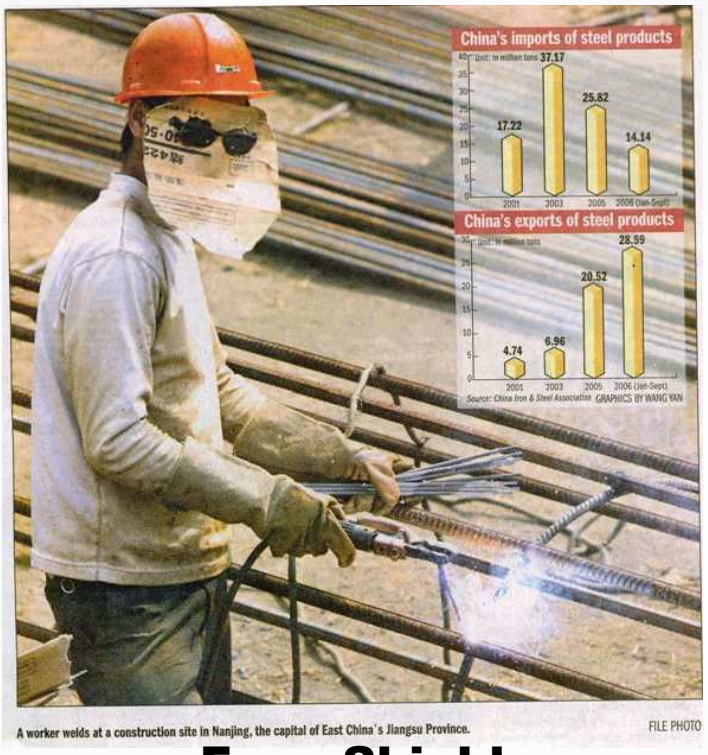
Effectiveness of Awareness Means

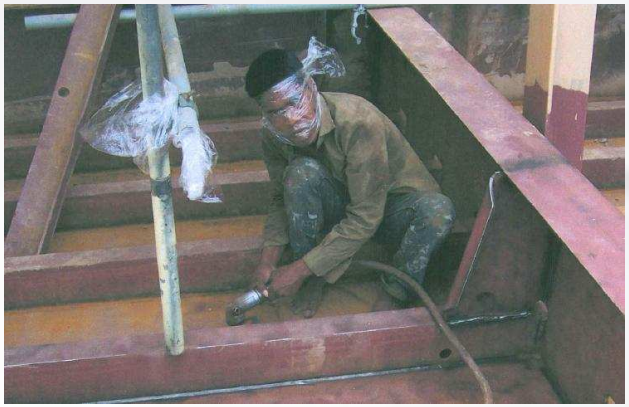
Effectiveness of Administrative Controls



Effectiveness of PPE



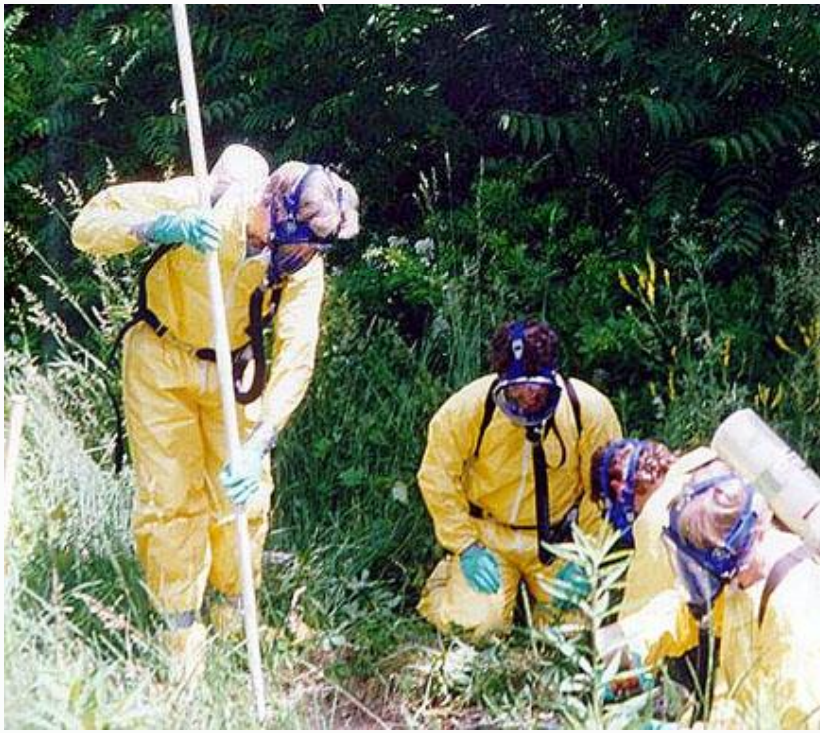
Face Shield

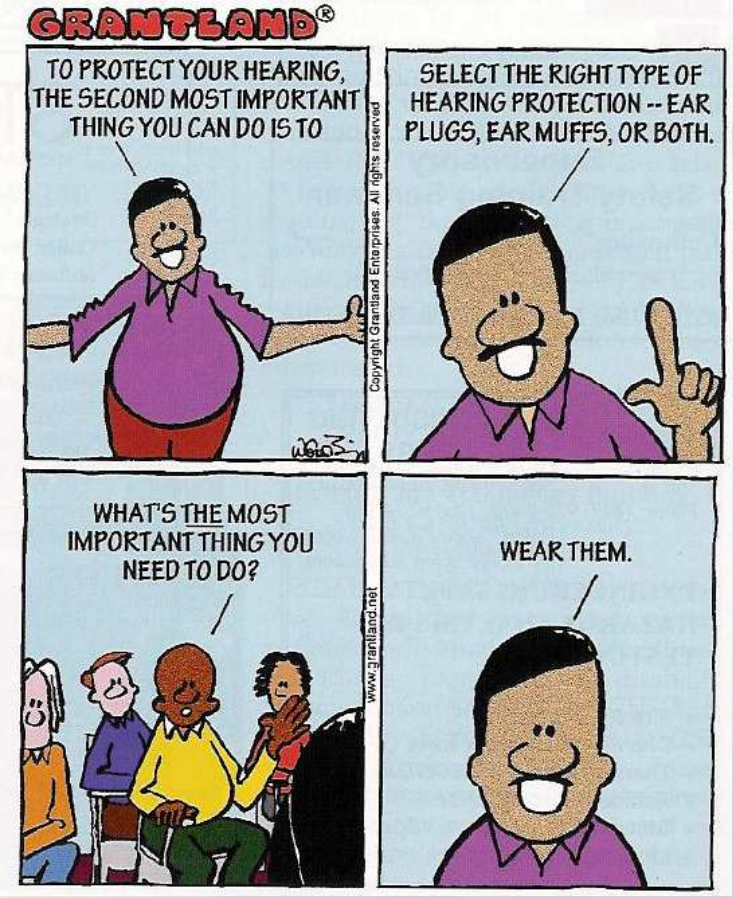


Dust Mask

Hard Hat

Effectiveness of PPE





Present Risk Reduction System

- The proposed system should be reviewed with the stakeholders involved before dedicating time, money and resources to the installation process

- If the safety system installed is improperly selected or applied for the application, the safeguards will be bypassed and the system will be ineffective

Accurately Estimate Implementation of the Proposed System

- It is important that the entire system be considered
  - Devices (interlock switches, light curtains, etc.)
  - Hardware (gates, posts, etc.)
  - Control system (safety monitoring relays, safety PLC, positive guided relays)
  - Wiring (conduit, etc.)

Proper Installation

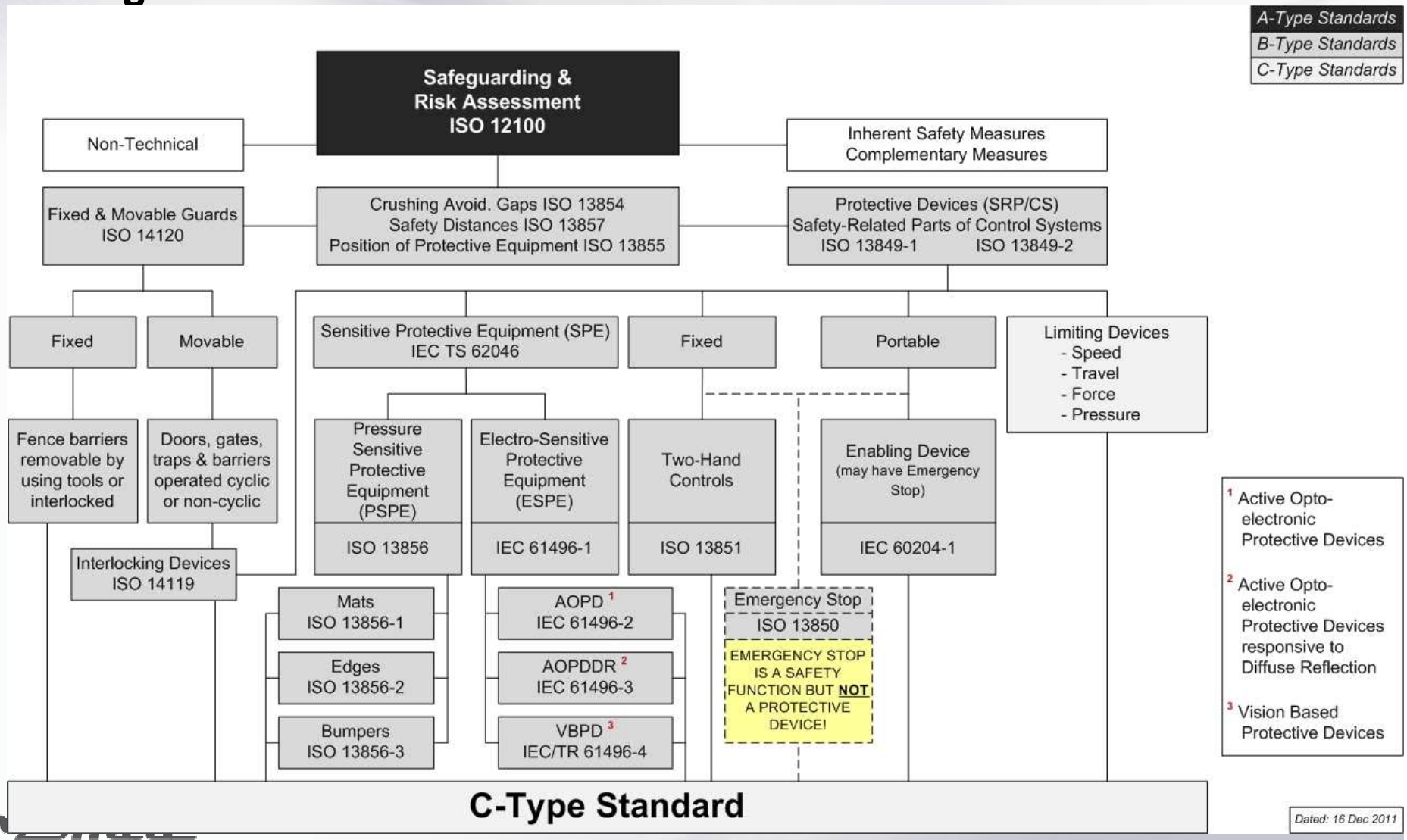
Proper installation is key to the reliability of the entire system

Use tried and true methods set forth by:

- Applicable national, regional, and local regulations
- Consensus standards
- Customer specifications
- Device and machine manufacturer's recommendations

Use devices rated for human safety (safety-rated)

Guidelines for the Selection and Application of Protective Devices According to ISO Standards



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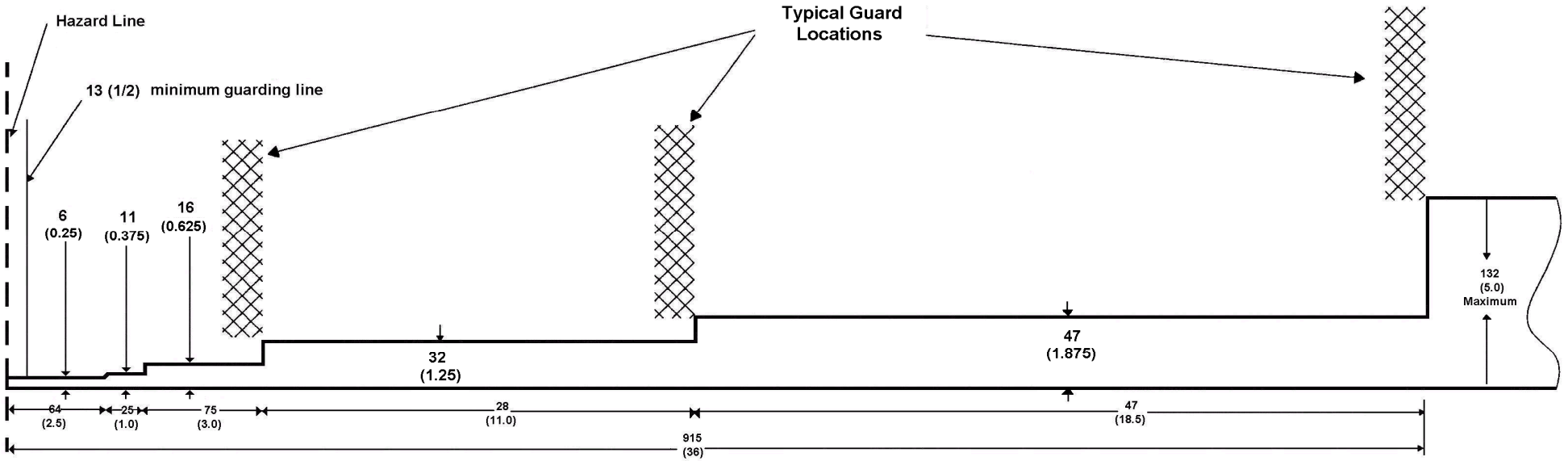
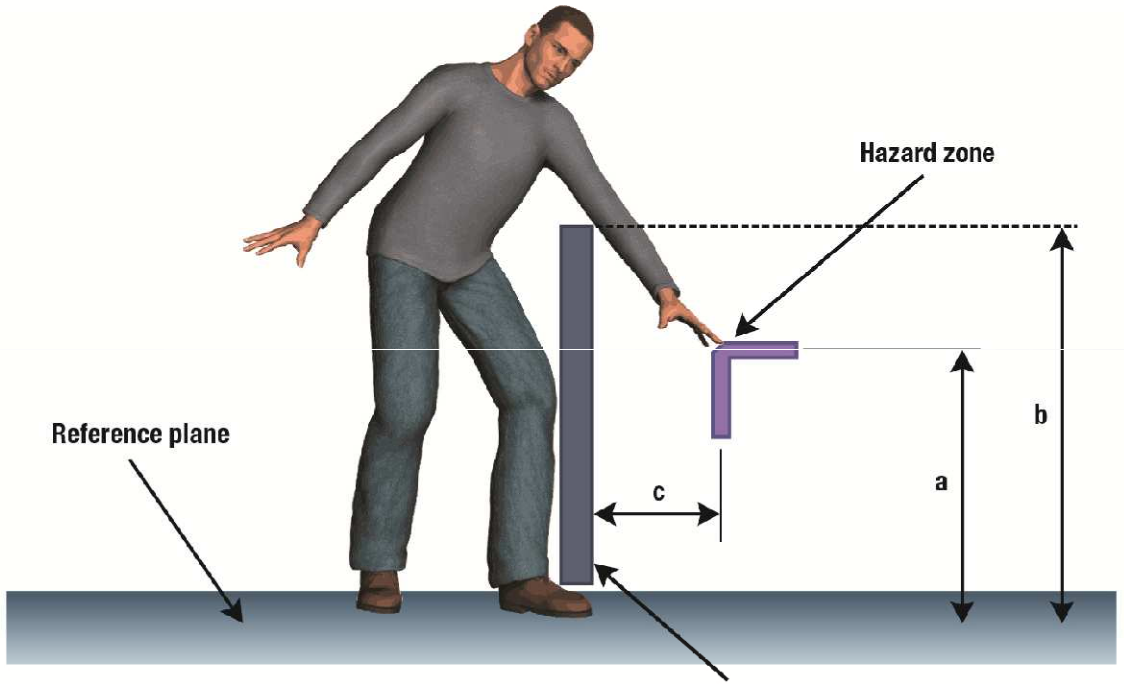
Set Back Distance of Barrier Guards



From ANSI B11.19-2003, Annex D

Barrier Height and Distance vs. Height of Hazard



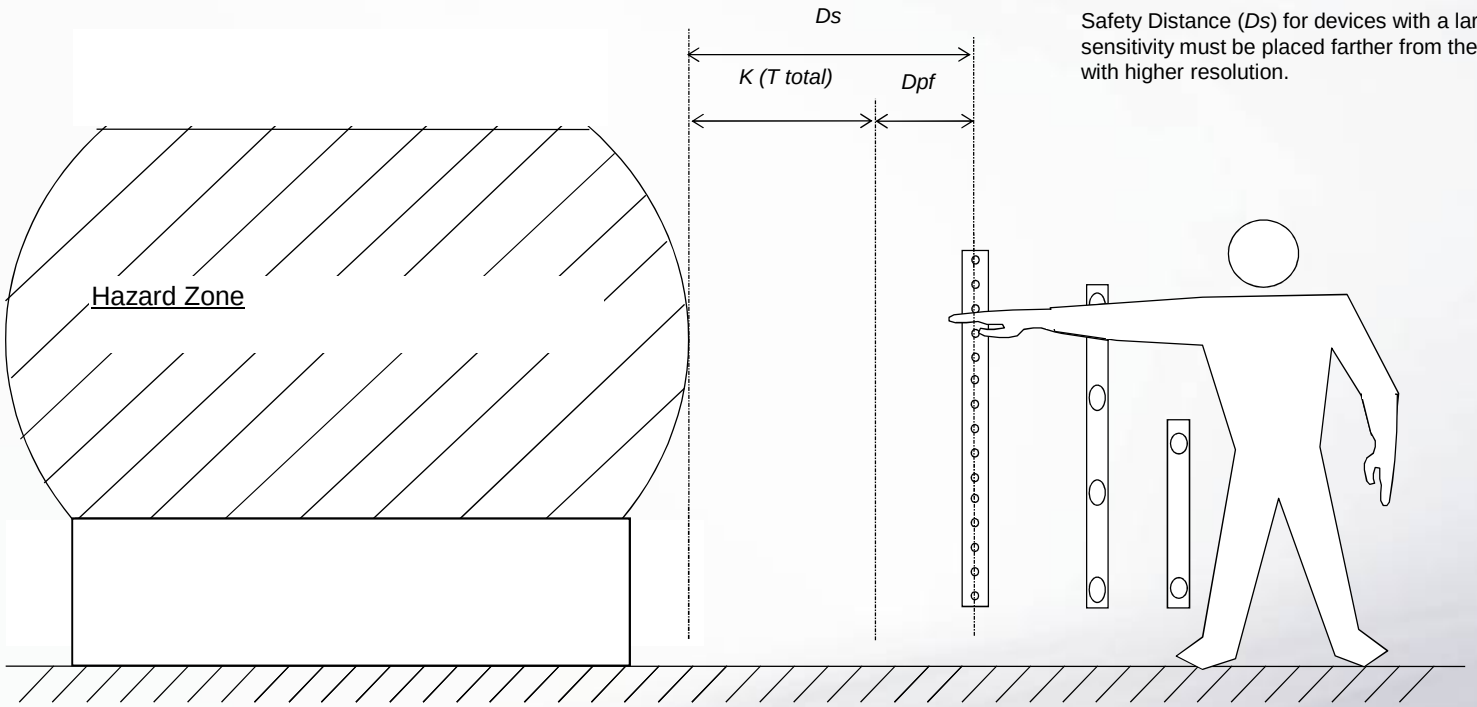
a – height of hazard zone
b – height of protective structure
c – horizontal safety distance to hazard zone

Guard height to protect against reach over

Safe Mounting Distance

$D_S = K (T) + D_{PF}$

Example of guarding with various object sensitivities



Safety Distance (*Ds*) for devices with a larger value for object sensitivity must be placed farther from the hazard than a device with higher resolution.

Image from ANSI B11.19-2003

Ensure Tolerable Risk is Achieved

- It is important to conduct a documented risk assessment both before and after safeguarding the machine / process

- If the residual risk is not tolerable after applying safeguards, conduct the process again

Zero Risk vs. Tolerable Risk

Many standards recognize that zero risk does not exist and cannot be attained

However, a good faith approach to risk assessment and risk reduction should achieve a tolerable risk level

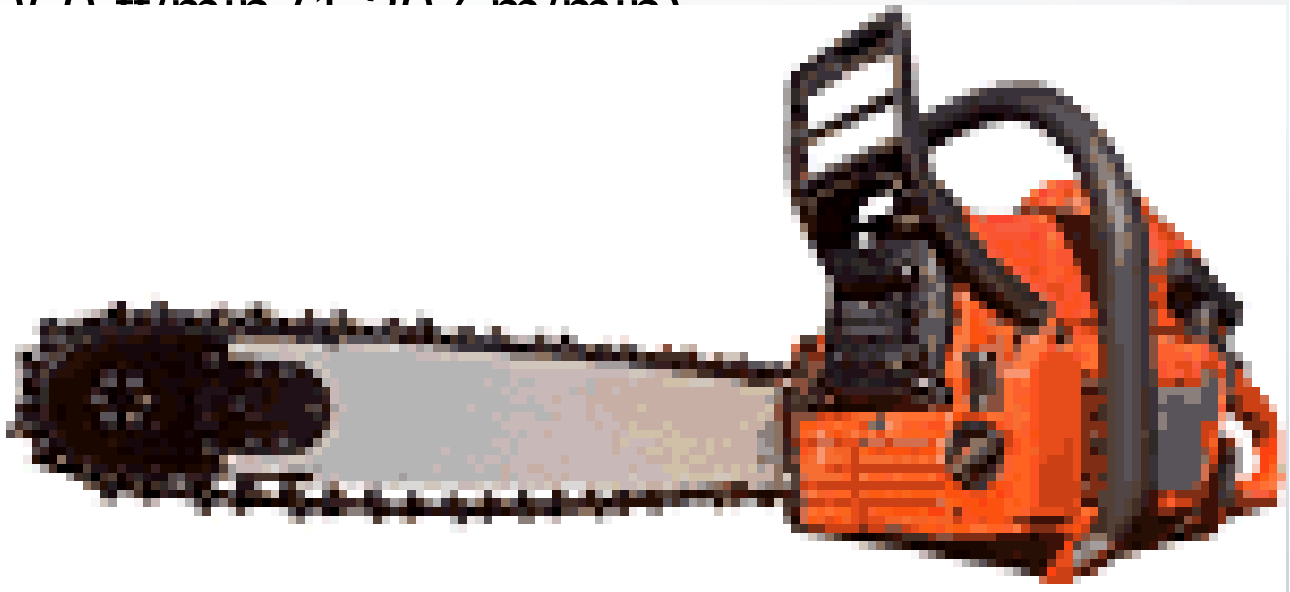
FYI: One of every 2 million deaths are caused by falling out of bed.

What is ‘Tolerable Risk’?

Example: A moving chain in close proximity to hands

Chain speed is 3,

- 45 mph (72 km/
- 66 ft/sec (20 m/



Is this tolerable?

If this risk is not tolerable, no chainsaw could ever be used.

Measuring Tolerable Risk

YES	NO	Can all of the following questions be answered with a YES?
☐	☐	Have all operating conditions and all intervention procedures been taken into account?
☐	☐	Has the method of hierarchy of control been applied?
☐	☐	Have hazards been eliminated or risks from hazards been reduced to the lowest practical level?
☐	☐	Is it certain that the measures taken do not generate new hazards?
☐	☐	Are the users sufficiently informed and warned about the residual risks?
☐	☐	Is it certain that the operator's working conditions are not jeopardized by the protective measures taken?
☐	☐	Are the protective measures taken compatible with each other?
☐	☐	Has sufficient consideration been given to the consequences that can arise from the use of a machine designed for professional / industrial use when it is used in a non-professional / non-industrial context?
☐	☐	Is it certain that the measures taken do not excessively reduce the ability of the machine to perform its function?

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Measuring Tolerable Risk

- ANSI B11.0-2010, Clause 6.7

  Achieve acceptable risk

  Once the residual risk has been established for each hazard, a decision shall be made to accept the residual risk, or to further reduce it.

  Risk reduction is complete when risk reduction measures are applied and acceptable risk has been achieved for the identified hazards. Achieving acceptable risk shall include reducing the likelihood of injury to a minimum. Additionally, achieving acceptable risk shall include, at a minimum, complying with local, regional, and national regulations.

  Informative Note: In all machinery applications, some level of residual risk exists.

Measuring Tolerable Risk

- ANSI B11.0-2010, Clause 6.7 (continued)
  Achieving acceptable risk will depend on:
  - the application of the hierarchy of controls (6.5.1.1 through 6.5.1.6);
  - the feasibility of the selected risk reduction measure(s).

    Informative Note 1: Risk assessment should facilitate a consistent decision making process. Qualified personnel are particularly important in decision making about acceptable risk.

    Informative Note 2: Acceptable risk is fundamentally a decision made by each supplier or user in the context of their own unique circumstances. The following structure is one example of a practical application of acceptable residual risk to relevant stakeholders:

    High residual risk – only acceptable when all reasonable alternatives/options (risk reduction measures) have been reviewed and formally deemed impracticable or infeasible. It is recommended that the group performing the risk assessment seek advice from additional safety or subject matter experts.

    Medium residual risk – undesirable but permissible only when all reasonable alternatives/options (risk reduction measures) have been formally deemed infeasible.

    Low residual risk – usually acceptable.

    Negligible residual risk – acceptable.

    Informative Note 3: See also, Annex F for additional information on achieving acceptable risk.

Close-out / Sign-off

- Conduct the following before releasing the machine for production:
  - Identify and document residual risk
  - Test for functionality
  - Document safe work procedures
  - Train personnel
  - Complete machine sign-off

Review

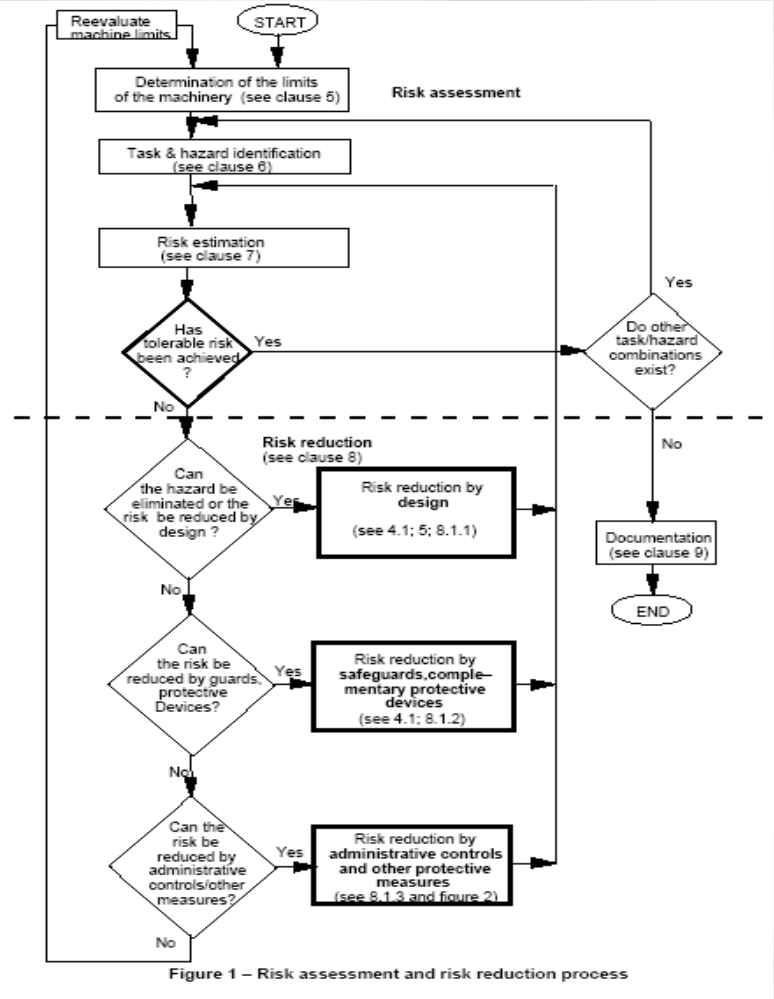
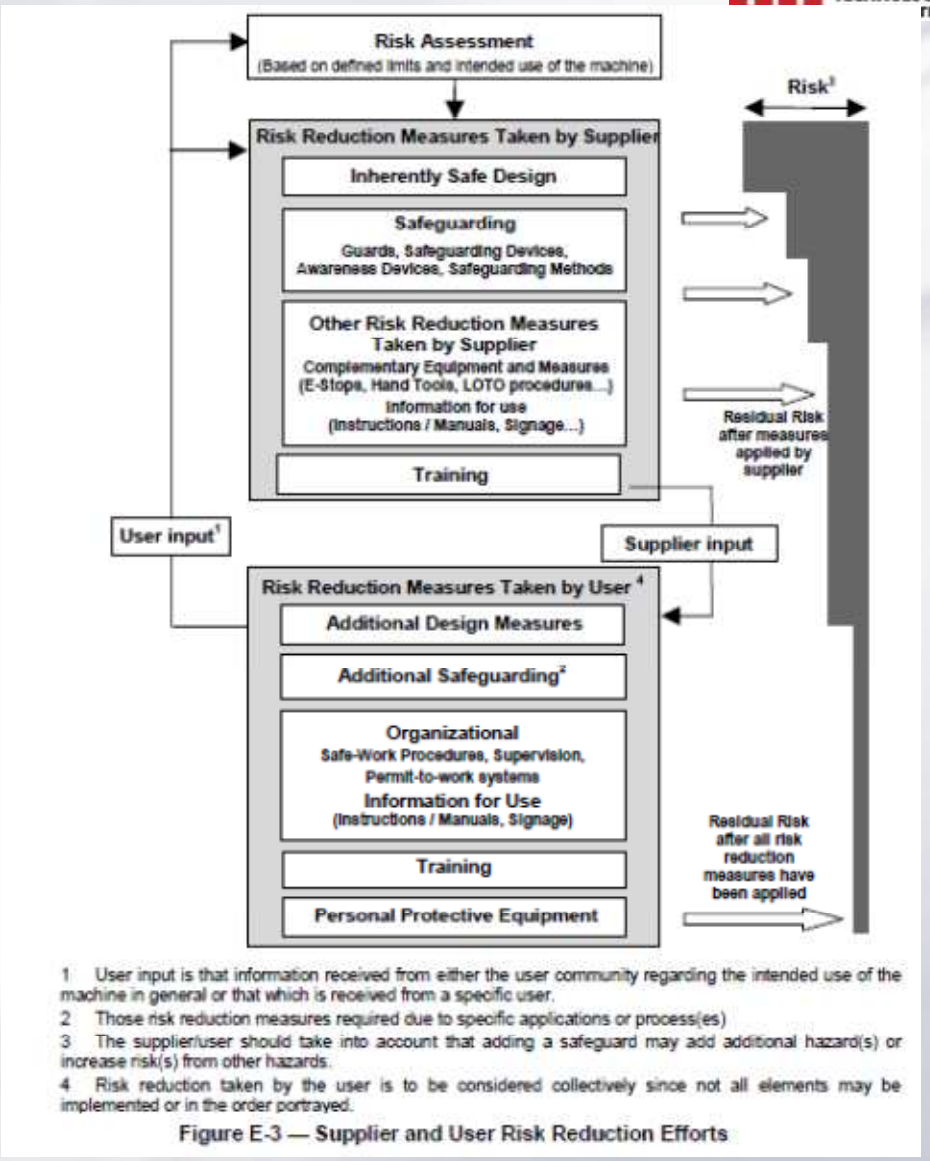


Figure 1 – Risk assessment and risk reduction process

Image from ANSI B11.TR3-2000



1 User input is that information received from either the user community regarding the intended use of the machine in general or that which is received from a specific user.

2 Those risk reduction measures required due to specific applications or process(es)

3 The supplier/user should take into account that adding a safeguard may add additional hazard(s) or increase risk(s) from other hazards.

4 Risk reduction taken by the user is to be considered collectively since not all elements may be implemented or in the order portrayed.

Figure E-3 — Supplier and User Risk Reduction Efforts

Image from ANSI B11.0-2010

The Omron STI Point System

Fig. 1.2 Remember: For this consideration we are presuming that an injury is inevitable and we are only concerned with its severity

1. THE SEVERITY OF POTENTIAL INJURY.

For this consideration we are presuming that the accident or incident has happened. Careful study of the hazard will reveal the most severe injury that can be reasonably conceived.

The severity of injury should be assessed as:

FATAL

MAJOR - (Normally irreversible) Permanent disability, loss of sight, limb amputation, respiratory damage etc.

SERIOUS - (Normally reversible) Loss of consciousness, burns, breakages etc.

MINOR - Bruising, cuts, light abrasions etc.

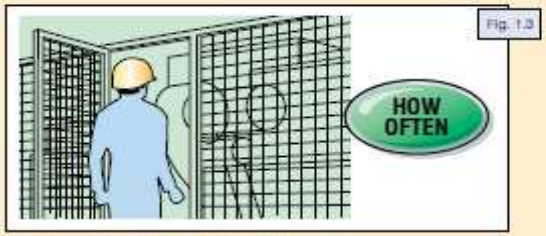


Fig. 1.3

2. FREQUENCY OF EXPOSURE

The frequency of exposure to hazard can be classed as :

FREQUENT - Several times per day.

OCCASIONAL - Daily.

SELDOM - Weekly or less.

Additional Factor	Suggested Action
More than one person exposed to the hazard.	Multiply the severity factor by the number of people.
Protracted time in the danger zone without complete power isolation.	If time spent per access is more than 15 minutes, add 1 point to the frequency factor.
Operator is unskilled or untrained.	Add 2 points to the total

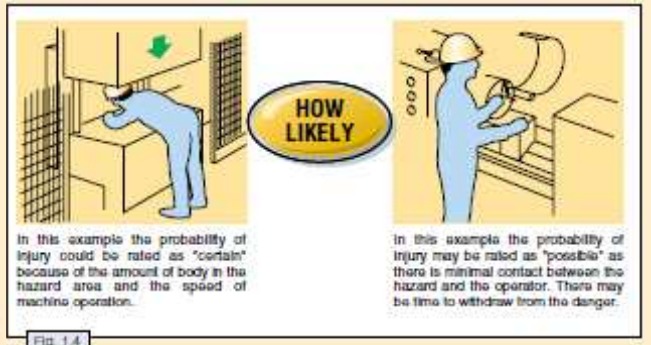
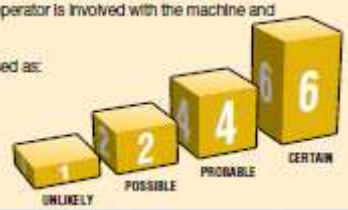


Fig. 1.4

3. PROBABILITY OF INJURY

You should assume that the operator is exposed to the hazardous motion or process.

By considering the manner in which the operator is involved with the machine and other factors such as speed of start up etc., the probability of injury can be classed as:



CERTAIN

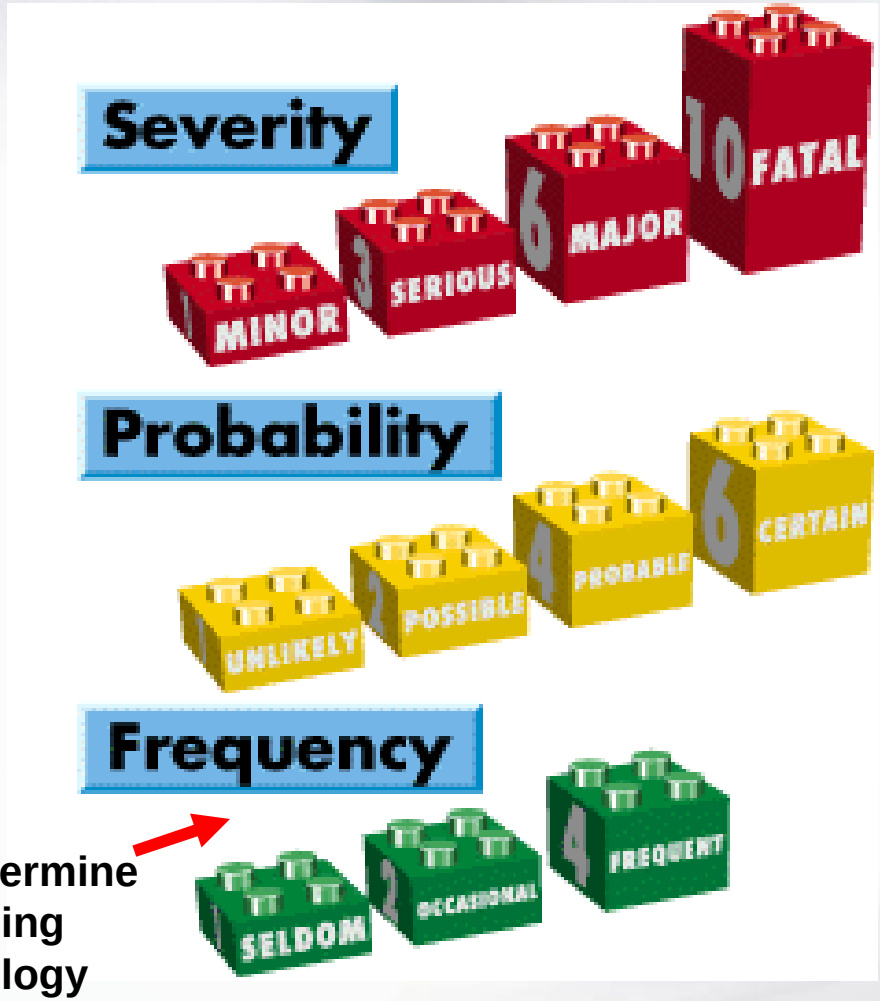
PROBABLE

POSSIBLE

UNLIKELY

Pages A8 & A9

Level of Risk



Helps Determine Guarding Technology

High

Cat 3-4, Control Reliable

Medium or Intermediate

Cat 2, Single Channel with Monitoring

Cat 1, ANSI Single Channel

Low

Add up to determine level of risk

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Risk Reduction Requirements

Identified Risk Level	Required Safeguard Performance	Required Circuit Performance *Definitions for ANSI/RIA R15.06-1999 (R2009)*
High (12+)	Barrier guard or safety-rated protective device (e.g. interlocked barrier guards, light curtains, safety mats, laser area scanners, or other presence sensing devices) preventing intentional exposure of any part of the body to the hazard by preventing access to the hazard or stopping the hazard. The guard or device shall be secured with special fasteners or a lock.	**Control Reliable** Control reliable safety circuitry shall be designed, constructed and applied such that any single component failure shall not prevent the stopping action of the equipment. These circuits shall include automatic monitoring at the system level. 1) The monitoring shall generate a stop signal if a fault is detected. A warning shall be provided if a hazard remains after cessation of motion; 2) Following detection of a fault, a safe state shall be maintained until the fault is cleared; 3) Common mode failures shall be taken into account when the probability of such a failure occurring is significant; 4) The single fault should be detected at time of failure. If not practicable, the failure shall be detected at the next demand upon the safety function.
Medium (7-11)	Barrier guard or safety-rated protective device (e.g. interlocked barrier guards, light curtains, safety mats, laser area scanners, or other presence sensing devices) preventing unintended exposure of any part of the body to the hazard by preventing access to the hazard or stopping the hazard. The guard or device shall not be removable or adjustable by unauthorized persons. This may also include physical devices that do not require adjustment or other operator intervention for use.	**Single Channel with Monitoring** Single channel with monitoring safety circuits shall include the requirements for single channel and be checked (preferably automatically) at suitable intervals. 1) The check of the safety function's) shall be performed: a) At machine start-up, and b) Periodically during operation; 2) The check shall either: a) Allow operation if no faults have been detected, or b) Generate a stop signal if a fault is detected. A warning shall be provided if a hazard remains after cessation of motion; 3) The check itself shall not cause a hazardous situation; 4) Following detection of a fault, a safe state shall be maintained until the fault is cleared.
Low (1-6)	Barrier guard or safety-rated protective device (e.g. interlocked barrier guards, light curtains, safety mats, laser area scanners, or other presence sensing devices) providing simple guarding against inadvertent exposure to the hazard. Examples include a fixed screen, chuck guard, or moveable barrier. This may include physical devices that require adjustment for use.	**Single Channel** Single channel safety circuits shall: 1) Include components which are safety-rated; 2) Be used in compliance with the manufacturers' recommendations and proven circuit designs (e.g. a single channel electromechanical positive break device which signals a stop in a de-energized state.)

Key elements of a useful safeguarding assessment and risk reduction report

Sample Assessment Report With Usable Information

Summary Spreadsheet for ABC Company - Somewhere, CA

792493-CS

Pg #	Asset Number	Manufacturer	Machine Type	Model Number	Serial Number	Location / Dept.	Highest Risk Score Before Guarding*	Highest PL_r**	Appears Compliant	Risk Level After Guarding***	Highest Prioritization Score to Establish Corrective Actions
23	EEE / FFF / GGG / HHH	Balance Tech. Inc. / XY Tool & Die	Widget Assembly Line (Balancer /	EEE / FFF / GGG / HHH	EEE / FFF / GGG / HHH	Assembly	42	d	No	A	27.3
42	CCC / DDD	Fanuc / Federal / Kingsbury	Robot Cell (Press, Robots, Assembly	CCC / DDD	CCC / DDD	Assembly	28	d	No	A	23
56	BBB	Bliss	Punch Press	BBB	BBB	Forming	14	e	No	A	13.72
62	AAA	HEM Inc.	Horizontal Band Saw	AAA	AAA	Machining	12	d	No	A	3.84
67	JJJ	Weld Wire	Welding Position Table	JJJ	JJJ	Welding	9	b	Yes	A	.09

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Executive Summary for ABC Company - Somewhere, CA

792493-CS

Assessment Results

In summary, Omron STI reviewed 5 machines to determine if they meet the minimum requirements for machine safeguarding. Of these 5 machines, 1 appears to be adequately guarded in accordance with our interpretation of the applicable equipment safeguarding requirements, but may require additional engineering review.

*Highest Classification by Initial Risk Levels

(4) HIGH risk machines (score of 12 or higher)
(1) MEDIUM risk machines (score of 7-11)
(0) LOW risk machines (score of 6 or lower)

** Highest Classification by Required Performance Levels

(1) PL, e
(3) PL, d
(0) PL, c
(1) PL, b
(0) PL, a

***Classification by Potential Residual Risk Levels

(5) Level A – Reduced Risk and Compliance Achieved
The residual risk level will be Low/Negligible and compliance with the appropriate standards will be achieved if the recommended risk reduction measures listed below are correctly implemented in accordance with the applicable requirements. The customer is responsible for ensuring that adequate training, supervision, and administrative controls are implemented and executed as necessary. This is based on Omron STI's experience and interpretation of the relevant safety standards.

(0) Level B – Reduced Risk but not Fully Compliant
The residual risk level will be Low/Negligible if the recommended risk reduction measures listed below are correctly implemented in accordance with the applicable requirements. However, the equipment will not meet full compliance with the appropriate standards due to the unique nature and special use of the equipment. The customer is responsible for ensuring that adequate training, supervision, and administrative controls are implemented and executed as necessary. This is based on Omron STI's experience and interpretation of the relevant safety standards.

(0) Level C – Lower Risk and Compliance Achieved
The residual risk cannot achieve a Low/Negligible level due to the unique nature and special use of the equipment, but it can be significantly reduced and compliance with the appropriate standards will be achieved if the recommended risk reduction measures listed below are correctly implemented in accordance with the applicable requirements. The customer must determine if the residual risk(s) still present is tolerable for the identified hazard(s) associated with the task(s) required by the customer to operate the equipment. The customer is responsible for ensuring that adequate training, supervision, and administrative controls are implemented and executed as necessary. This is based on Omron STI's experience and interpretation of the relevant safety standards.

(0) Level D – Lower Risk but not Fully Compliant
The equipment will not meet full compliance with the appropriate standards and the residual risk cannot achieve a Low/Negligible level due to the unique nature and special use of the equipment, but the residual risk can be significantly reduced if the recommended risk reduction measures listed below are correctly implemented in accordance with the applicable requirements. The customer must determine if the residual risk(s) still present is tolerable for the identified hazard(s) associated with the task(s) required by the customer to operate the equipment. The customer is responsible for ensuring that adequate training, supervision, and administrative controls are implemented and executed as necessary. This is based on Omron STI's experience and interpretation of the relevant safety standards.

Optional Stop Time Measurement

Of the 5 machines assessed, 3 require a stop time measurement to determine the adequate safe mounting distance of presence sensing devices. This proposal includes Omron STI performing this service at our standard labor rate. However, a Stop Time Measurement device can be purchased to allow your facility to conduct the periodic measurements required for compliance with appropriate regulations. Please contact John Peabody at 714-809-0197 to obtain a quotation for this device.

Machine De

Machine Detail

Plant Name:
ABC Company

Location:
Somewhere, CA

Machine Manufacturer:
Balance Tech. Inc. / XY Tool & Die /

Machine Type:
Widget Assembly Line (Balancer / Rivet

Machine Model:
EEE / FFF / GGG / HHH

Machine Serial Number:
EEE / FFF / GGG / HHH

Machine Asset Number:
EEE / FFF / GGG / HHH

Machine Location/Dept.:
Assembly

Applicable Vertical (Machine Specific) Standards [See page 6 for additional information]:

ANSI B11.20 ANSI/ASME B20.1

Emergency Stop Recommendations

Category (per NFPA 79): 1 - Controlled stop with power to the machine actuators available to achieve the stop then remove power when the stop is achieved
Circuit Performance: Single Channel with Monitoring

Estimated Residual Risk Level

Level A – Reduced Risk and Compliance Achieved

The residual risk level will be Low/Negligible and compliance with the appropriate standards will be achieved if the recommended risk reduction measures listed below are correctly implemented in accordance with the applicable requirements. The customer is responsible for ensuring that adequate training, supervision, and administrative controls are implemented and executed as necessary. This is based on Omron STI's experience and interpretation of the relevant safety standards.

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OMRON STI SAFETY, TECHNOLOGY

Plant Name: ABC Company
Location: Somewhere, CA
Machine Manufacturer: Balance Tech. Inc. / XY Tool &
Machine Type: Widget Assembly Line (Balancer
Machine Model: EEE / FFF / GGG / HHH
MachineSerial Number: EEE / FFF / GGG / HHH
Machine Asset Number: EEE / FFF / GGG / HHH
Machine Location/Dept: Assembly

Safety Function / Zone(s): Cell Interior

Risk Evaluation

Description of Task(s) Evaluated:

- Restarting the machine after stopping / interruption
- Mounting or changing tools, tool-setting
- Housekeeping
- Control/Inspection
- Process Changover

Hazards:

- Mechanical - Crushing
- Mechanical - Cutting or severing
- Mechanical - Stabbing or puncturing
- Mechanical - Entanglement
- Mechanical - Shearing
- Mechanical - Drawing-In or trapping
- Mechanical - Abrasion or friction

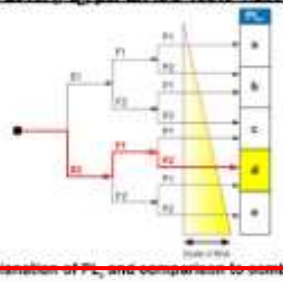
Description of Hazard(s):
There are crushing, shearing, cutting, entanglement, and abrasion hazards at various points of operation within the assembly line.

Initial Risk Score and Level per Omron STI Methodology
The initial risk evaluation is performed assuming no safeguarding measures are in place or the existing safeguarding has failed to an unsafe condition.

Severity:	Major(6)	X No. of People Exposed: 1	= 36
Frequency:	Frequent (4)		2
Probability:	Probable(4)		4
Other Factors:	☐ Unskilled/Untrained Operator (0)		0
	☐ Protracted Time in Danger Zone w/out Power Isolation (0)		+ 0
Risk Score Before Guarding:			42 RISK LEVEL HIGH

See Table 5 of Assessment Process for safeguard and circuit performance requirements.

Required Performance Level (PL_r) per EN ISO 13849-1:2006: PLd



Review Figure 2 for further explanation of PL and comparison to combinations of Categories and selection of components.

Plant Name: ABC Company
Location: Somewhere, CA
Machine Manufacturer: Balance Tech. Inc. / XY Tool &
Machine Type: Widget Assembly Line (Balancer
Machine Model: EEE / FFF / GGG / HHH
MachineSerial Number: EEE / FFF / GGG / HHH
Machine Asset Number: EEE / FFF / GGG / HHH
Machine Location/Dept: Assembly

Safety Function / Zone(s): Cell Interior

Priorization Score to Establish Corrective Actions

The Prioritization Score for this machine is 27.30 and is provided to present further information to help determine a corrective action plan. This value is based upon the following common safeguarding categories evaluated for compliance at the time of our assessment.

Basic Safeguarding Categories Evaluated for Compliance

CATEGORY	COMPLIANCE ACHIEVED
Point of Operation / Perimeter Guards:	No
Point of operation guards are missing, misapplied, or not securely fastened. Individuals can reach over, under, around or through the guards to the point of operation or the guards are missing or can be easily removed.	
Mechanical Power Transmission Guards:	Yes
All mechanical power transmission apparatuses below 8' have guards which appear to be compliant at this time.	
Safety Control System:	No
The existing control system does not use safety-rated components, such as safety monitoring relays, force guided relays, or a safety-rated PLC.	
Safety-Rated Devices:	Yes
All components of the safety system are rated for human safety and have been tested and listed for such use.	
Emergency Stop Devices:	No
The emergency stop devices: - are missing; or - are not self-latching; or - do not use non-retentive relays; or - do not have red actuators; or - are not active in all modes; or - are not Type 0 or Type 1 stop circuits; or - are guarded or not readily accessible; or - are not mushroom style (for pushbuttons); or - do not have slack detection or are mounted without springs (for cable pulls).	
Energy Isolation Devices:	Yes
All required energy isolation devices appear to be compliant at this time.	
Electrical Drop-Out Protection:	Yes
The electrical control system has been tested for the required drop-out protection.	

792469-CS

Plant Name:
ABC Company

Location:
Somewhere, CA

Machine Manufacturer:
Balance Tech. Inc. / XY Tool &

Machine Type:
Widget Assembly Line (Balancer

Machine Model:
EEE / FFF / GGG / HHH

MachineSerial Number:
EEE / FFF / GGG / HHH

Machine Asset Number:
EEE / FFF / GGG / HHH

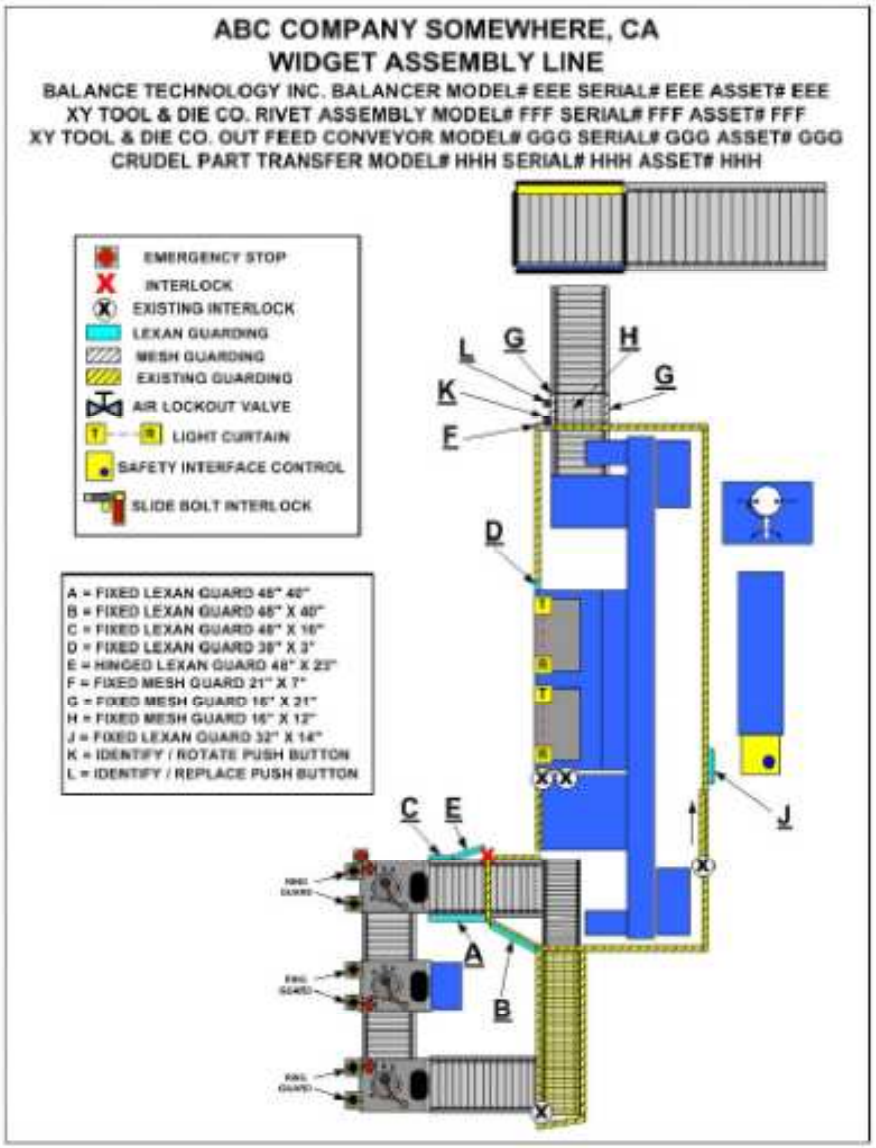
Machine Location/Dept:
Assembly

Risk Reduction (Safeguarding) Recommendations

Install yellow legend plates on the existing emergency stop pushbutton devices for compliance. Replace the existing light curtains at the load/unload stations with safety-rated devices and install covers on the existing optical two hand control devices to prevent unintentional actuation. The perimeter barrier guards will be augmented to prevent contact with the hazardous moving equipment by reaching around, under, through, or over the guards. A hinged interlocked guard will be installed at the conveyor and a fixed tunnel guard will be installed at the out feed conveyor to prevent access to the part transfer equipment. The existing pushbutton station at the out feed conveyor will be rotated to prevent intentional bypassing by personnel. All safety-rated devices will be integrated to a safety interface control.

See plan view drawing for location of guards and controls.

792469-CS-1



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Commercially Available Risk Assessment Software Packages

- CIRSMA™ (Corporate Industrial Risk and Safety Management Application) by *Industrial Safety Integration* www.cirsma.com
- Designsafe® by *design safety engineering* www.designsafe.com
- RiskSafe by *Dyadem* www.dyadem.com

Let's review

- What is a risk assessment and why do I have to do it?
  - A comprehensive evaluation of the hazards associated with a machine.
    - It must be repeatable and documented
  - Do it to insure compliant risk reduction

- Who can do a risk assessment?
  - A qualified vendor or in-house resources
- How do I do it?
  - Follow the 12 step process

Let's Review

- What is the difference between risk assessment and risk reduction?
  - Risk Assessment identifies the hazards and exposure
  - Risk Reduction applied safeguards and processes to mitigate the risks identifeid
- What tools are available?
  - There are a wealth of third party software products
  - None do the job for you, you must have expertise

Questions?