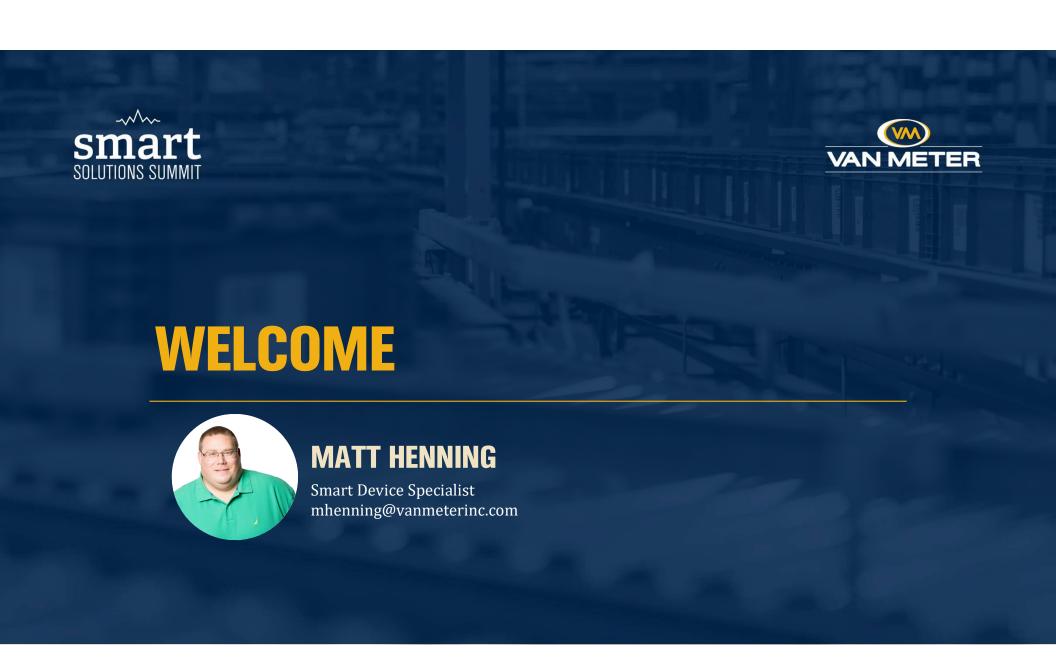


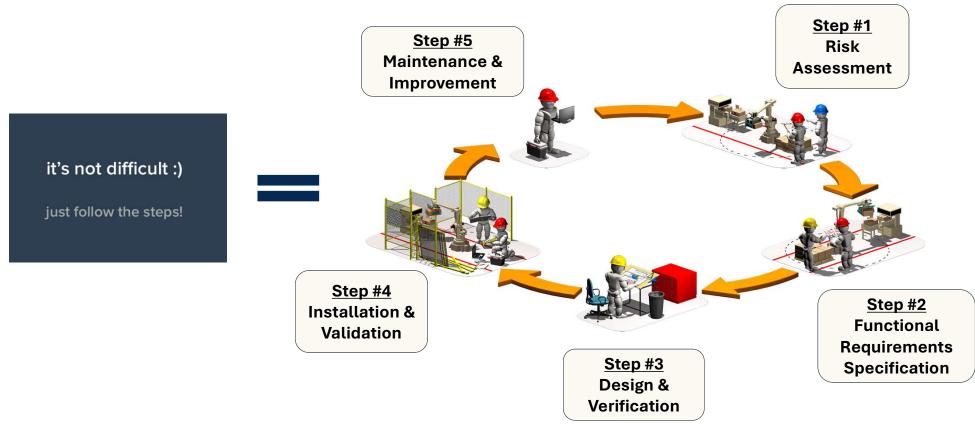
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HOW RISKY IS YOUR BUSINESS?
INTRODUCTION TO RISK ASSESSMENTS
& SAFETY FUNCTION DESIGN





MACHINE SAFETY – SAFETY LIFE CYCLE



Step #5 Maintenance & Improvement

THE DIAGNOSIS

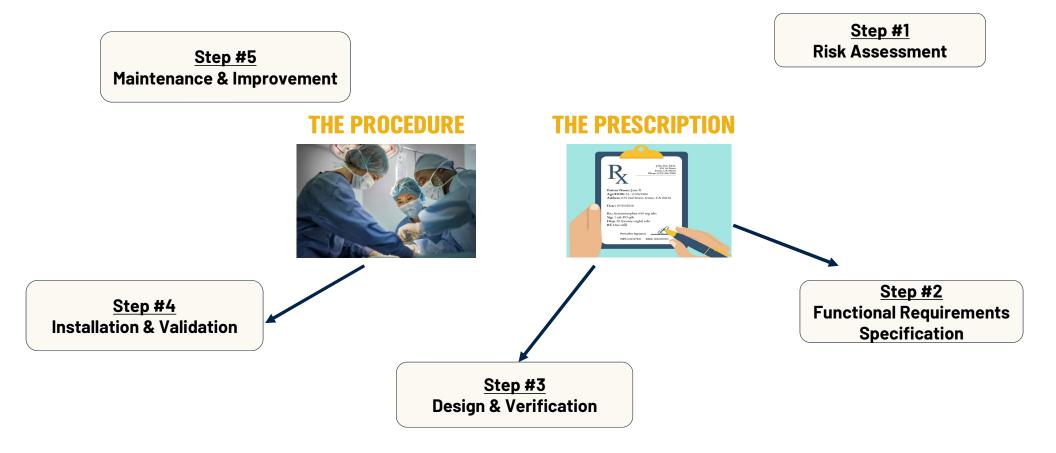
Risk Assessment

Step #4
Installation & Validation

Step #3
Design & Verification

Step #2
Functional Requirements
Specification

Step #1



Step #5 Maintenance & Improvement

MANAGING CHANGE

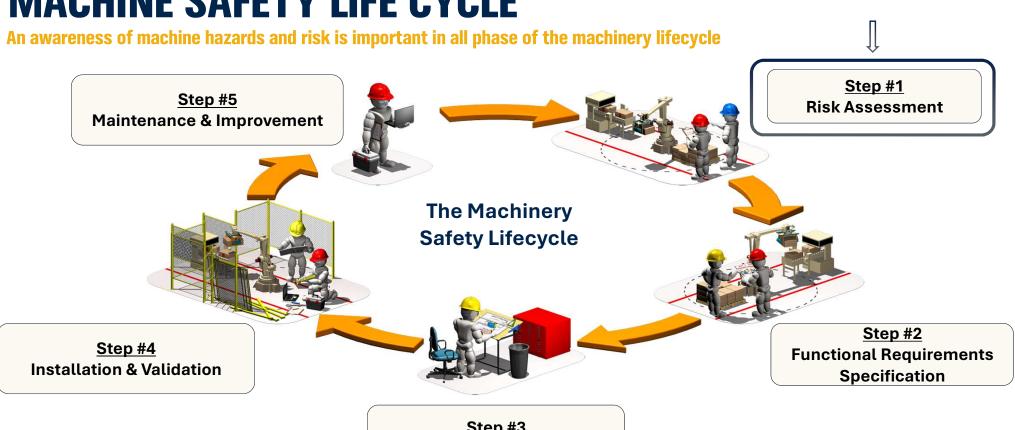
Step #1 Risk Assessment

Step #4
Installation & Validation

MEDICAL CHECK UP

Step #3
Design & Verification

Step #2
Functional Requirements
Specification



Step #3
Design & Verification

WHY RISK ASSESSMENT?

REQUIRED BY MANY REGULATORY BODIES

National regulatory agencies reference risk assessment for essential health and safety requirements. "Risk should be assessed and reduced"

- Standards referencing Risk Assessment
 - ANSI B11.0
 - ISO 12100
 - ANSI 7244.1
 - ANSI B11.19
 - ANSI RIA 15.06
 - NFPA 79
 - And the list goes on...

BECAUSE WE NEED A GOOD ANSWER AS TO WHY WE DESIGNED THE SYSTEM THE WAY WE DESIGNED IT...

Examples of bad answers...

- I don't know.
- The other machines are all wired that way.
- We have always done it that way.
- The OEM takes care of that for us.

ARE RISK ASSESSMENTS REQUIRED? YES!

IEC 610508-1 – Functional safety of electrical/electronic/programmable electronic safety-related systems For hardware safety integrity it is necessary to apply quantified reliability estimation techniques in order to assess whether the target safety integrity, as determined by the risk assessment, has been achieved, taking into account random hardware failures (see IEC 61508-2, 7.4.5).

RIA 15.06 – Industrial Robots and Robot System Requirements "A Risk Assessment shall be performed and is no longer optional" "Selection of a category 0 or category 1 stop (in accordance with IEC60204-1) function shall be determined from the risk assessment"

ISO 13849 - Safety of Machinery (PL)

"From the risk assessment (see ISO 12100) at the machine, the designer shall decide the contribution to the reduction of risk which needs to be provided by each relevant safety function which is carried out by the SRP/CS(s)."

NFPA 79 – Electrical Standard for Industrial Machinery "The risks associated with the hazards identified by the risk assessment shall be reduced such that the safety performance determined by the risk assessment is met"

IEC 62061 - Safety of Machinery (SIL)

"5.2.4.1 The safety integrity requirements for each SRCF shall be derived from the risk assessment to ensure the necessary risk reduction can be achieved. In this standard, a safety integrity requirement is expressed as a target failure value for the probability of dangerous failure per hour of each SRCF."

ANSI B11.19 – Performance Requirements for Safeguarding "Selection of the safeguarding requires task and hazard identification, and the application of documented risk assessment and risk reduction of the total production system."



RISK DEFINITION

RISK

is a function of

severity of harm

and

only changes with design

Probability of Occurrence

- Exposure of person to hazard
- Occurrence of hazardous event
- Possibility to avoid or limit harm

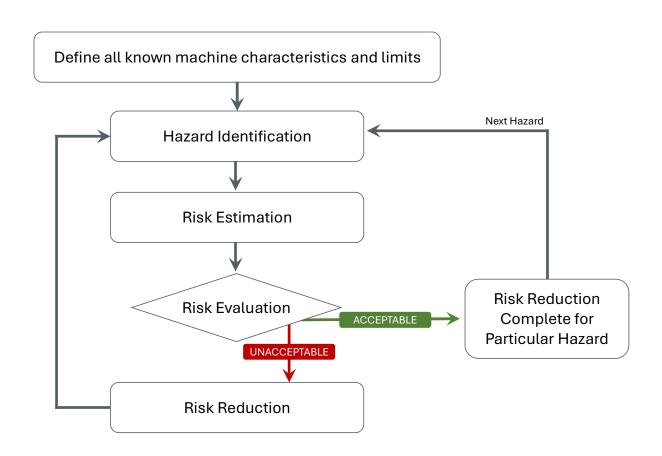
THE PURPOSE OF RISK ASSESSMENT

- The process serves as an effective tool for properly **identifying** and **assessing** the **real hazards** involved in operating a particular machine.
- Risk assessment provides a method for determining **equivalent levels of protection** when designing safeguards and stating OSHA's minor service exception.
- The process takes away the guesswork when estimating risk and prescribing safety system performance.
- Risk assessment is an active, **documented process** that can be filed and maintained for the entire life of the machine, and serves as documented proof of your "due diligence".
- Risk assessment establishes the **foundation** and early **framework** for the design and implementation of an **effective machine safety program**.

WHY ARE TEAM BASED RISK ASSESSMENTS POWERFUL TOOLS IN REDUCING RISK IN THE WORKPLACE?

- Knowledgeable people involved in the team-based process
- The process is repeatable
- Identifies hazards that are associated with the workplace
- Identifies different approaches to reducing risk
- Document for review and future changes
- Industry Safety Standards <u>require</u> that the hazards be identified and reduced

THE PROCESS



JJO Can you please make this bigger to fill the slide? Joyce, Jessica, 2025-04-01T16:48:14.204

DEFINE MACHINE CHARACTERISTICS AND LIMITS

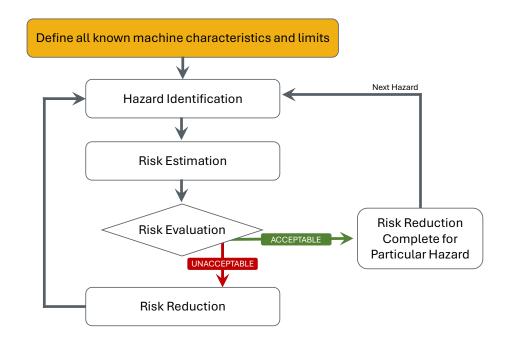
BASIC PROJECT MANAGEMENT - TEAM GATHERS DATA AND DEFINE A CLEAR PROJECT SCOPE.

Scope

- · Operational states (auto, manual)
- Specific tasks (loading/unloading, maintenance)
- A specific portion of the lifecycle (installation, operation)
- Who can be harmed (public, personnel)
- What can be damaged (people, equipment, environment).

Limits

- Use limits (operating modes, number of persons)
- Space limits (material flow, access points)
- Time limits (production cycles, device wear)
- Environmental (temperature, humidity)



HAZARD IDENTIFICATION

A CRITICAL STEP. IDENTIFY 'REASONABLY FORESEEABLE' TASKS AND HAZARDS

Tasks

How people interact with the machine to identify how they could be harmed. Intended use and reasonably foreseeable misuse of the machine

Example tasks:

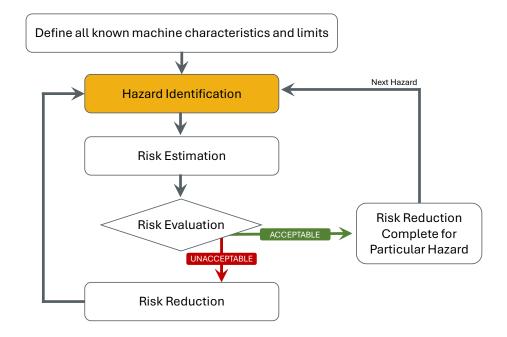
- · Packing and transportation
- Unloading / unpacking
- Systems installation and assembly
- Start-up / commissioning
- Set-up / changeover
- Operation (all modes)
- Maintenance

Hazards

Reasonably foreseeable hazards and hazardous situations shall be identified.

Example hazards:

- Mechanical hazards
- Energy sources
- Slips and falls
- Hot surfaces
- Sharp edges
- Example hazardous situations: Equipment failure, Operator error



HAZARD IDENTIFICATION

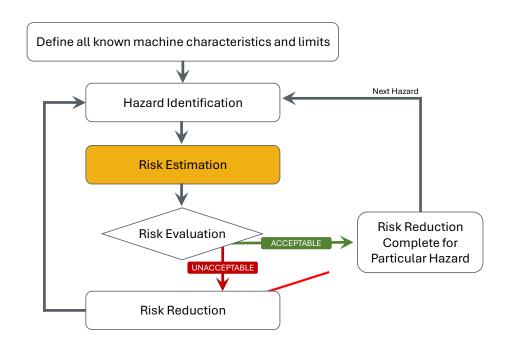
- Machine Hazards Lists:
 - ISO 12100:2010 Annex B
 - ANSI B11.0:2020 Annex D

Table B.1

No	Type or	Examples	of hazards	Subclause of this	
,	group	Origin ^a	Potential consequences ^b	International Standard	
1	Mechanical hazards	acceleration, deceleration; angular parts; approach of a moving element to a fixed part; cutting parts; elastic elements; falling objects; gravity; height from the ground; high pressure; instability; kinetic energy; machinery mobility; moving elements; rotating elements; rough, slippery surface; sharp edges; stored energy;	being run over; being thrown; crushing; cutting or severing; drawing-in or trapping; entanglement; friction or abrasion; impact; injection; shearing; slipping, tripping and falling; stabbing or puncture; suffocation.	6.2.2.1 6.2.2.2 6.2.3 a) 6.2.3 b) 6.2.6 6.2.10 6.3.1 6.3.2 6.3.3 6.3.5.2 6.3.5.4 6.3.5.5 6.3.5.6 6.4.1 6.4.3 6.4.4	
2	Electrical hazards	vacuum. arc; electromagnetic phenomena; electrostatic phenomena; live parts; not enough distance to live parts under high voltage; overload; parts which have become live under fault conditions; short-circuit; thermal radiation.	burn; chemical effects; effects on medical implants; electrocution; falling, being thrown; fire; projection of molten particles; shock.	6.2.9 6.3.2 6.3.3.2 6.3.5.4 6.4.4 6.4.5	
3	Thermal hazards	explosion; flame; objects or materials with a high or low temperature; radiation from heat sources.	burn; dehydration; discomfort; frostbite; injuries by the radiation of heat sources; scald.	6.2.4 b) 6.2.8 c) 6.3.2.7 6.3.3.2.1 6.3.4.5	

RISK ESTIMATION

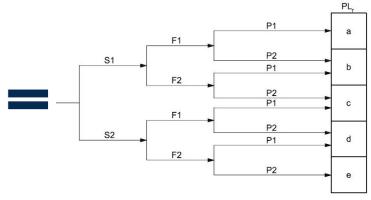
- Needs to happen BEFORE risk reduction
- A combination of <u>severity of harm</u> and the <u>probability</u> of occurrence
- Risk Scoring Each task/hazard pair must be scored to derive a risk level.



HRN - Hazard Rating Number

PE Pro	bability of Exp	osure				Frequency	of Exposure	e
0	Impossible	C	Cannot happen			0.1	Infre	quently
1	Unlikely	TI	Though conceivable			0.2 Annua		ially
2	Possible	b	ut unusual			1 Monthl		thly
5	Even chance		uld happer	n		1.5	Wee	kly
8	Probable	n	ot surprised	i		2.5	Daily	
10	Likely	to	be expecte	ed		4	Hour	ly
15	Certain	n	doubt			5 Constantly		tantly
МРН	Maximum Prob	able Loss				NP Numbe	er of Person	s at risk
0.1	Scratch or bruise					1	1-2 p	ersons
0.5	Laceration or	mild ill hea	lth effect			2	3-7 p	ersons
1	Break of a mi	inor bone or	minor illne	ess (temporai	у)	4	8-15	persons
2	Break of a ma	ajor bone or	minor illne	ss (permane	nt)	8	16-5) persons
4	Loss of Limb	, eye / serio	us illness of	a temporary	nature	12	50 +	persons
	Loss of Limb	s, eyes / ser	ious illness	of permanen	t nature			
8								
_	Fatality							
8 15 RISK	Fatality Negligible	Very Low	Low	Significant	High	Very High	Extreme	Unacceptable

Performance Level Required PLr



ISO 13849 - PLR

Severity of the hazard.

- S1: Slight (normally reversible injury)
- S2: Serious (normally irreversible injury or death)

Frequency and/or exposure to hazard.

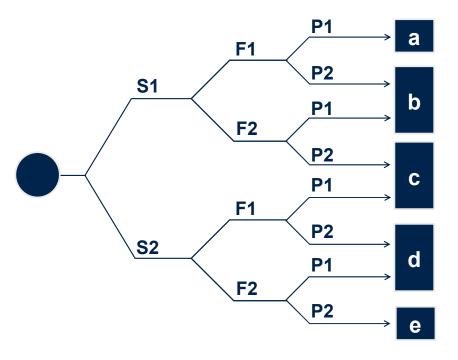
- F1: Seldom to less often and/or exposure time is short
- F2: Frequent to continuous and/or exposure time is long

Possibility of avoiding the hazard or limiting harm.

- P1: Possible under specific conditions
- P2: Scarcely possible

*Note: ISO 13849-1 is not considered an assessment methodology

Performance Level, PLr



HAZARD RATING NUMBER (HRN)

	LO Likelihood of Occurrence				
0	Impossible	cannot happen			
0.1	Almost unlikely	possible in extreme circumstances			
0.5	Highly unlikely	though conceivable			
1	Unlikely	but could occur			
2	Possible	but unusual			
5	Even chance	could happen			
8	Probable	not surprised			
10	Likely	to be expected			
15	Certain	no doubt			

FE Frequency of Exposure		
0.1	Infrequently	
0.2	Annually	
1	Monthly	
1.5	Weekly	
2.5	Daily	
4	Hourly	
5	Constantly	

LO x FE x DPH x NP=H.R.N.

	DPH Degree of Possible Harm
0.1	Scratch or bruise
0.5	Laceration or mild ill health
1	Break of a minor bone or minor illness (temporary)
2	Break of a major bone or minor illness (permanent)
4	Loss of limb/eye/serious illness of a temporary natury
8	Loss of limbs/eyes/serious illness of a permanent nature
15	Fatality

NF	NP Number of Persons			
1	1-2 persons			
2	3-7 persons			
4	8-15 persons			
8	16-50 persons			
12	50+ persons			

Risk	Negligible	Very Low	Low	Significant	High	Very High	Extreme	Unacceptable
HRN	0-1	1-5	5-10	10-50	50-100	100-500	500-1000	Over 1000

IEC 62061 - SIL

Severity (Se)			Class (CI)		
Γ	4	5-7	8-10	11-13	14-15
4	SIL 2	SIL 2	SIL 2	SIL 3	SIL 3
3		(OM)	SIL 1	SIL 2	SIL 3
2			(OM)	SIL 1	SIL 2
1	Ï			(OM)	SIL 1

$$CI = Fr + Pr + Av$$

Frequency of exposure	(see A.2.4.1)
A) ≥ 1 per h (A)	5
< 1 per h to ≥ 1 per day	5
< 1 per day to ≥ 1 per 2 weeks	4
< 1 per 2 weeks to ≥ 1 per year	3
< 1 per year	2

Frequency and duration of exposure (Fr)

Probability of occurrence	Probability (Pr)
Very high	5
Likely	4
Possible	3
Rarely	2
Negligible	1

Consequences	Severity (Se)
Irreversible: death, losing an eye or arm	4
Irreversible: broken limb(s), losing a finger(s)	3
Reversible: requiring attention from a medical practitioner	2
Reversible: requiring first aid	1

Probabilities of avoiding or limiting harm (AV)				
Impossible	5			
Rarely	3			
Probable	1			

RIA TR15.306

Factor	Rating	Criteria (Examples) – choose most likely Read criteria from the top for each factor
	Serious \$3	Normally non-reversible; likely will not return to the same job after recovery from incident: - fatality - limb amputation - long term disability - chronic illness [f any of the above are applicable, the rating is SERIOUS]
Injury Severity	Moderate S2	Normally reversible, likely will return to the same job after recovery from incident:
	Minor S1	First aid; no recovery required before returning to job: - bruising - small cuts - no loss time (multi-day) - does not require attention by a medical doctor If any of the above are applicable, the rating is MINOR
200	Prevented E0	Exposure to hazard(s) is effectively mitigated by design. Use of guards prevents exposure or access to the hazard(s) (see Part 2, 5.10). If an interlocked guard is selected, the third bullet must also be met. If functional safety is used as a risk reduction measure, the functional safety performance (PL), meets or exceeds the required functional safety performance (PL). See Part 2, 5.2. If any of the above are applicable, the rating is PREVENTED
Exposure	High E2	Typically more than once per day or shift Frequent or multiple short duration Durations/situations which could lead to task creep and does not include teach If any of the above are applicable, the rating is HIGH
	Low E1	Typically less than or once per day or shift Occasional short durations If either of the above are applicable, the rating is LOW
	Not possible A3	Insufficient clearance to move out of the way and safety-rated reduced speed control is not used The robot system or cell layout causes the operator to be trapped, with the escape route toward the hazard Safeguarding is not expected to offer protection from the process hazard (e.g. explosion or eruption hazard) If any of the above are applicable, the rating is NOT POSSIBLE
Avoidance	Not likely A2	insufficient clearance to move out of the way and safety-rated reduced speed control is used obstructed path to move to safe area hazard is moving faster than reduced speed (250 mm/sec) inadequate warning/reaction time the hazard is imperceptible If any of the above are applicable, the rating is NOT LIKELY
	Likely A1	sufficient clearance to move out of the way hazard is incapable of moving greater than reduced speed (250 mm/sec) adequate warning/reaction time positioned in a safe location away from the hazard If any of the above are applicable, the rating is LIKELY

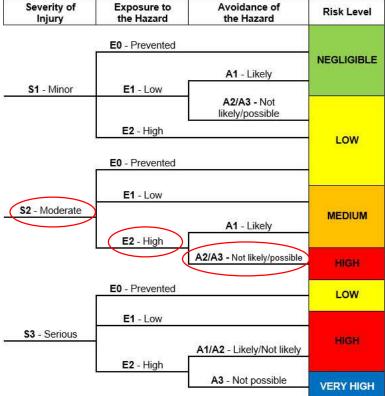


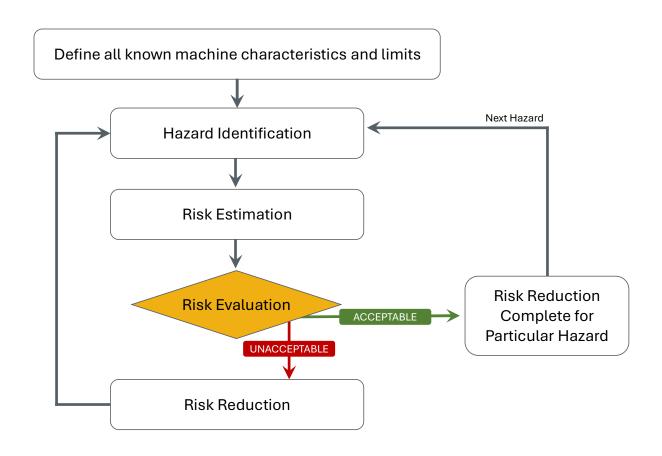
Table 5 – Minimum functional safety performance

Risk Level	PL	Structure Category				
NEGLIGIBLE (see 6.5.3.1)	b	39				
LOW	С	2				
MEDIUM	d	2				
нівн	d	3				
VERY HIGH (see 6.5.3.2)	е	4				

RISK ASSESSMENT EXAMPLE

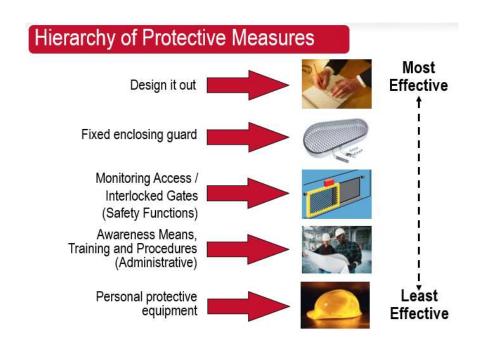
Task Type	Area	Task Specific	Injury Type	Body Parts Affected	Origin / Cause	Energy / Hazard Source	s I	E	A	Initial Risk Rating	PLr	Cat. Structure	Current Safeguards	Recommendations	s	E	A	Residual Risk Rating
Normal Operation	3. East Side	3. Normal Operation	Mech: Entanglement	Fingers, hands	18. Spur gears	Electrical	\$3 E	E1 A	А3	HIGH	PLd	3	during normal operation. LOTO procedures in place - central location that operators have access to, pre-	[System Redesign] - Upgrade circuitry to Cat 3 [Engineered Solution] - Add movable guarding with gate door to extend between machines with mechanical means of escape. Add locking gate switch that requires both adjacent machines to be shut down before entering area. Must move electrical disconnect to outside of guarding. Install trapped key system to gate switches. Add compliant Estops. [Training/Procedures] - Include new guarding in training and procedures for machine. If guarding is removed, machine must be under LOTO [Awareness] - Post signage for hazard, paint guards safety yellow [PPE] - N/A	\$3	EO ,	A1	LOW
Normal Operation	3. East Side	3. Normal Operation	Mech: Entanglement	Fingers, Hands	19. Roller drive gear box shafts	Electrical	S3 E	E1 /	A3	нібн	PLd	3	machine prevents full body access to shafts. Possibly able to reach over guarding to hazard. [Training/Procedures] - Building has restricted access during normal operation. LOTO procedures in place - central location that operators have access to, pre-harvest training (once per year) on all applicable procedures. SOP (work instruction) in place, pre-	[System Redesign] - Upgrade circuitry to Cat 3 [Engineered Solution] - Add movable guarding with gate door to extend between machines with mechanical means of escape. Add locking gate switch that requires both adjacent machines to be shut down before entering area. Must move electrical disconnect to outside of guarding. Install trapped key system to gate switches. Add compliant Estops. IF new guarding is placed behind ladder, add fixed guarding to prevent access to hazards. [Training/Procedures] - Include new guarding in training and procedures for machine. If guarding is removed, machine must be under LOTO [Awareness] - Post signage for hazard, paint guards safety yellow [PPE] - N/A	\$3	EO ,	A1	LOW

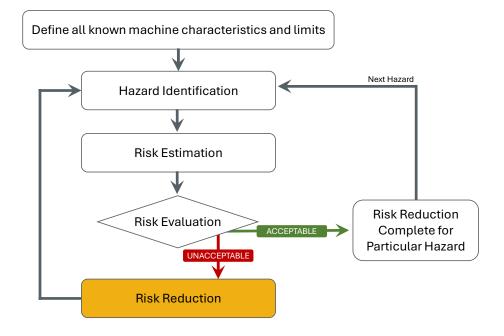
THE PROCESS



REDUCE RISK: SAFELY AND EFFICIENTLY

If the risk level is not acceptable, risk reduction measures can be implemented using the Hazard Control Hierarchy.





RESIDUAL RISK WITH RISK REDUCTION

Residual risk - The risk remaining after risk reduction measures are taken.

HRN - Hazard Rating Number

PE Pro	obability of Exp	osure				Frequency	of Exp	osure			
0	Impossible		annot happe	en		0.1		Infrequently			
1	Unlikely	Th	nough conce	eivable		0.2		Annually			
2	Possible	bı	ut unusual		1		Monthly				
5	Even chance	cc	uld happer	1		1.5		Week	ly		
8	Probable	ot surprised		2.5		Daily					
10	Likely	to	be expecte		4		Hourly				
15	Certain	ne	doubt			5	5 Constantly				
МРН	Maximum Prob	able Loss				NP Numbe	r of Pe	ersons	at risk		
0.1	Scratch or br					1 1-2 persons					
0.5	Laceration or	mild ill hea	lth effect			2 3-7 persons					
1	Break of a mi	Break of a minor bone or minor illness (temporary)						8-15	oersons		
2	Break of a ma	ajor bone or	minor illne	ss (permane	nt)	8		16-50	persons		
4	Loss of Limb	, eye / serio	us illness of	a temporary	nature	12 50 + persons					
8	Loss of Limb	s, eyes / ser	ious illness	of permanen	t nature						
•	E 1 101										
	Fatality										
15 RISK	Negligible	Very Low	Low	Significant	High	Very High	Extre	me	Unacceptable		

Hazard Identification

Risk Estimation

Risk Evaluation

ACCEPTABLE

Risk Reduction

Complete for Particular Hazard







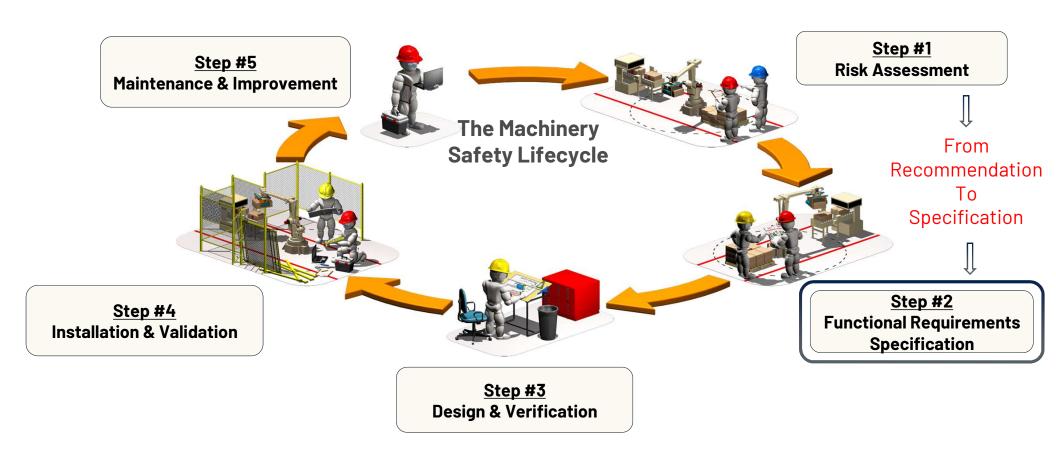
ISO 13849 RISK REDUCTION

FNTFR RESIDUAL RISK INTO WORKSHFFT

Task Type	Area	Task Specific	Injury Type	Body Parts Affected	Origin / Cause	Energy / Hazard Source	s	E A	4	Initial Risk Rating	PLr	Cat. Structure	Current Safeguards	Recommendations	S E	A	Residual Risk Rating
Normal Operation	3. East Side	3. Normal Operation	Mech: Entanglement	Fingers, hands	18. Spur gears		s3 [PLd arc	³ l reco	[Engineered Solution] - Fixed guarding on side of machine prevents full body access to spur gears. Possibly able to reach over guarding to hazard. [Training/Procedures] - Building has restricted access during normal operation. LOTO procedures in place-central location that operators have access to, preharvest training (once per year) on all applicable mmendations in place of the properties of the process of	System Redesign] - Upgrade circuitry to Cat 3 [Engineered Solution] - Add movable guarding with gate door to extend between machines with mechanical means of escape. Add locking gate switch that requires both adjacent machines to be shut down before entering area. Must move electrical disconnect to outside of guarding. Install trapped key system to gate switches. Add compilant Estops. [Training/Procedures] - Include new guarding in training and procedures for machine. If guarding is removed, machine must be under LOTO [Awareness] - Post signage for hazard, paint guards safety yellow [PPEI - N/A	\$3 E) A1	LOW
Normal Operation	3. East Side	3. Normal Operation	Mech: Entanglement	Fingers, Hands	19. Roller drive gear box shafts		s3 i				_{РLd}	³ aram	[Engineered Solution] - Fixed guarding on side of machine prevents full body access to shafts. Possibly able to reach over guarding to hazard. [Training/Procedures] - Building has restricted access during normal operation. LOTO procedures in place - central location that operators have access to, preharvest training (once per year) on all applicable eters affected by the final hearing protection	Inew guarding is placed behind ladder, add fixed zards.	\$3 E) A1	LOW

3. Evaluate the residual risk, and determine if acceptable

An awareness of machine hazards and risk is important in all phase of the machinery lifecycle



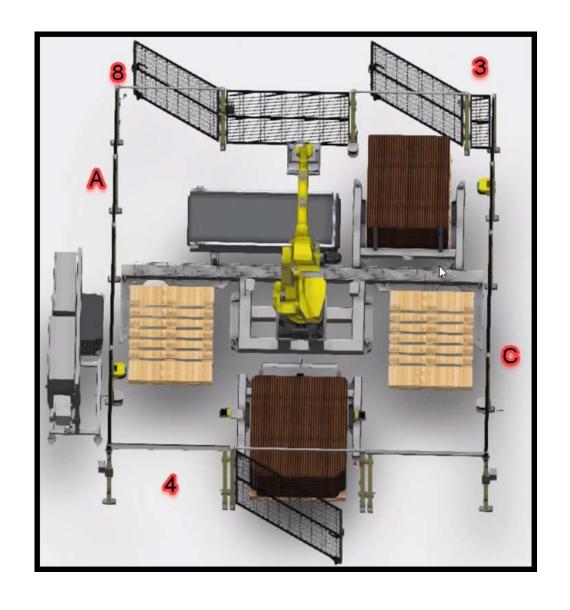
SAFETY SYSTEM FUNCTIONAL REQUIREMENTS

DETAILS THE INFORMATION FROM THE RISK ASSESSMENT

Detailed design document used by the engineer to understand how to....

- Design circuits and software to the appropriate Performance Level as well as hard guarding requirements
- Design the circuit to function correctly in all modes of operation.
 - Manual, Auto, Teach, when muted, how to reset etc..
- Serves as a basis for all activities to follow in the safety design process!
- We create our validation procedures based on this document!

SAFETY SYSTEM FUNCTIONAL REQUIREMENTS



DETAILED SAFETY FUNCTION DESIGN

SF1: SAFETY FUNCTION SPECIFICATION

Safety Function Name:

Guard Door 1 (op side) Protective stop and prevention of restart of the conveyor

when opened

Performance Level Requirement (PLr): Per ISO 13849-1 Annex A: PLb

Type of Safety Function: Safety-related stop initiated by safeguard

Operating Modes: Automatic & Manual

Triggering Event: Opening of the Guard Door

Safety Reaction: Initiate a Category 0 Stop

Safe State: Conveyor Stopped

Number of Operations: 2/Hour @ 365 Days/Year = 17,520/year

Fault Reaction: Initiate an STO and annunciate the fault

Faults Considered and/or Excluded: Broken Guard Door Switch Actuator

Response Time/Distance Consideration: N/A – Locking Guard Door

The conveyor is exposed with a stop time of 1 second. A distance calculation is not applicable due to the minor injury potential.

Safety Function Requirements:

Opening of the guard door will initiate a Category 0 stop of the conveyor and prevent an unintended restart by removal of power to the motors via the drive STO feature. The stop time must not exceed 1 second. Upon closing of the door, motion of the conveyor and bottle feed belts will not resume until the reset pushbutton is pressed and released. Faults at the door interlock switch, wiring terminals or drive will be detected by the safety relay before the next safety demand and inhibit a reset of the safety function.

Interface to Other Safety Functions:

This will not degrade the Sleever feeder/cutter function and the

Emergency Stop will override this safety function

Verification/Validation Document Reference: TBD – Validation Document Page

Other Document References: TBD - Electrical Print Numbers

DETAILED GUARDING DESIGN

