

# **Machine Guarding & Functional Safety for External Suppliers**

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## 1 Scope

The purpose of this document is to outline the TE Connectivity BASIC MINIMUM requirements for machinery safety for the design of new machines as well as existing machines. This document is considered as supplementary to the safety standards listed in section 2.

The requirements set forth in this standard shall be considered minimum requirements; sites shall ensure that all requirements ascribed by local, regional, or national regulatory agencies or any other authority having jurisdiction are met or exceeded.

This document covers:

- New Custom Machinery
- Existing Machinery upgrades
- Modifications to existing machinery
- Relocation of existing machinery
- All machinery & equipment being installed and utilized in a TE Connectivity facility

This document provides guidance on the following requirements:

- Risk Assessment
- Risk Evaluation
- Risk Reduction
- Safeguarding Requirements
- Verification & Validation
- Documentation Requirements

See <u>TEC-124-98</u> for additional requirements for New Custom-Built Assembly Machines and New Custom-Built Non-Assembly machines.

## 1.1 Purpose and Content

This document shall be used to implement functional safety. The goal is to eliminate or minimize risks of potential hazards associated with required tasks while documenting the process and decisions.

This document has been created using the requirements of various ANSI/ISO/IEC Functional Safety standards. They include standards for risk assessments (ANSI B11.0 / ISO 12100), risk reduction (ANSI B11.19 / ISO13849, ISO13855, ISO13857, ISO14120), and verification and validation requirements outlined in ISO13849-1 & 2, and IEC 62061. If a machine type has a type C standard and the requirements of the type C standard differ from this document, then the type C standard takes precedence.

A key fundamental of this standard is the requirement for Machinery to be compliant to the following.

- It is mandatory that Machinery is legally compliant to the Country and Regional regulations, not only in the country of manufacture but also in the country of use.
- This specification applies wherever machine hazards are present within TE that may expose a person to the risk of injury.
- This standard does not cover AGV's.

#### 1.2 Application

This specification is applicable to all facilities globally within TE Connectivity (TE). No new, modified, or re-built machine or equipment may be put into production without Qualified TE Personnel or qualified 3<sup>rd</sup> party reviewing the proposed safety system design and documentation to ensure compliance with this specification. Safety reviews are encouraged during the design phase of a project to avoid costly and timely machine changes on-site prior to being placed into production.

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**TE qualified personnel** refers to either a TE employee or an authorized third party representing TE, who possesses the technical expertise to understand and interpret this document for the purpose of verifying a machine's compliance. For example, a TUV Certified TE employee.

If equipment has a moving part powered by pneumatic, electrical, hydraulic, or other energy source, then it is a machine and is subject to the requirements of this document. The intent is to cover industrial machinery and equipment used in TE sites. It is not intended to cover office equipment, hand tools, or powered industrial trucks.

The term "machinery" also covers an assembly of machines which are arranged and controlled so that they function as an integral whole.

If equipment does not have moving parts, then it is not considered a machine as defined and covered by this standard; however, some equipment may have no moving parts (e.g., a heat exchanger) which should still be risk assessed for safety using either this document or a process hazard analysis (PHA) approach.

#### NEW CUSTOM-BUILT MACHINES and NEW CUSTOM-BUILT ASSEMBLY MACHINES

Shall meet the requirements of this standard as well as additional requirements outlined in <u>TEC-124-98</u>.

#### CATALOG or OFF-THE-SHELF MACHINES

These machines are typically designed for general use and can typically be purchased from a catalog or internet site with no modifications. These machines are typically mass produced, available for immediate purchase, and are available to the public for purchase and use. This specification does apply to Off the Shelf or Catalog Machines to ensure the machine is safe for our employees to operator and maintain. Off the shelf machines are still subject to standards required by law such as UL or CE. TE will accept the safety documentation "as delivered" with these machines and the safety documentation shall be reviewed by Qualified TE Personnel. If safety documentation is not available, then a safety review of the machine shall be conducted by Qualified TE Personnel prior to machine being placed in production.

## EXISTING MACHINES - UPGRADES, REBUILDS, REFUBISHING, or MODIFICATIONS

Any modifications to a machines safety functions, guarding, or layout shall follow the machinery safety lifecycle and procedures outlined in this standard.

## STAMPING, MOLDING, PLATING MACHINES

Any machine governed by a "C" level ANSI/ISO/IEC standard shall follow the rules of the "C" level standard. If this machine is integrated into a larger workcell, then the integration of multiple machines into a larger machine or workcell shall follow the procedures outlined in this document.

Stamping machines are governed by "C" level standard such as ANSI B11.1 or ISO16092 which takes precedent over this standard. However, when integrating auxiliary equipment with a stamping machine such as de-reelers, reelers, inspection stations, lasers, etc... This specification does apply to the joining of these multiple machines into one larger machine or workcell,

Molding machines are governed by "C" level standard such as ANSI B151.1 or ISO20430 which takes precedent over this standard. However, when integrating auxiliary equipment with a molding machine, this specification does apply to the joining of these multiple machines into one larger machine or workcell,

Plating lines have process/chemical hazards as well as machinery hazards. The machine portion of a plating line shall meet the requirements of this specification. Machine portion includes moving parts that are powered by pneumatic, electrical, hydraulic, or other

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energy sources. This includes auxiliary equipment such as de-reelers, reelers, or inspection stations.

#### 1.2.1 Waivers and Deviation

If a supplier is unable to comply with the requirements an exemption (noncompliance) or waiver (alternative method of compliance) shall be submitted to site or BU EHS Lead or BU/site Ops Lead for consideration of approval.

The purpose of the request for waivers and deviations is to ensure that a formal procedure for capturing variances or deviations from the requirements of the standard are implemented. Typically, the request for waiver is submitted by the project team.

For example, if a third-party piece of equipment is being brought to the site for a short time and does not meet all the requirements of the standard, then the site can apply for a variance.

A waiver or deviation requires that a risk assessment is performed, and a decision is made as to whether to allow this piece of equipment to be used. Temporary safeguards and safety procedures may need to be implemented to ensure the equipment was safe.

Granting a waiver does not mean that equipment can continue to run if it is not safe. The purpose of a waiver is to allow a short-term waiver from requirements for business reasons. It is not a process to be used frequently. It shall only be applied in rare cases when the full impact, risks, and consequences have been thoroughly reviewed and approved.

#### 2 Reference Documents and Forms

The following list identifies material available in support of this Standard including External Regulatory citations or directives, and TEC standards, specifications, and forms.

## 2.1 Regulatory

When an ANSI/ISO/IEC safety standard is referenced in this document, it refers to the most recent version.

- A. Control of Hazardous Energy Lock-Out / Tag-Out
  - U.S. OSHA § 1910.147 The control of hazardous energy (lockout/tagout)
  - ANSI Z244.1 The Control of Hazardous Energy Lockout, Tagout, and Alternative Methods
  - ISO 14118 Safety of machinery Prevention of unexpected start-up
- B. Functional Safety Design & Risk Reduction
  - ISO 13849-1 Safety of machinery Safety-related parts of control systems Part 1: General principles for design
  - EN 62061 Safety of machinery Functional safety of safety-related electrical, electronic and programmable electronic control systems (IEC 62061:2005)
  - ANSI B11.19 Performance Requirements for Risk Reduction Measures: Safeguarding and Other Means of Reducing Risk
  - U.S. OSHA 29CFR 1910 Subpart O, Machinery and Machine Safeguarding
- C. Industrial Robots
  - ISO 10218-1 Robots and robotic devices Safety requirements for industrial robots -Part 1: Robots

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- ISO 10218-2 Robots and robotic devices Safety requirements for industrial robots -Part 2: Robot systems and integration
- ISO/TS 15066 Robots and robotic devices Collaborative robots
- ANSI R 15.06 Industrial Robots and Robot Systems Safety Requirements
- RIA TR R15.406 Technical Report for Industrial Robots & Robot Systems: Safeguarding
- ANSI/RIA 15.06 Article 10.7.7, CSA Z434-03 Article 10.7.8
- ANSI RIA TR R15.606 Robots & Robotic Devices Collaborative Robots

#### D. Laser Safety

- IEC 60825
- ANSI Z136

#### E. Physical Guards

#### Fixed:

- ISO 14120 Safety of machinery Guards General requirements for the design and construction of fixed and movable guards
- ANSI B11.19 Performance Requirements for Risk Reduction Measures: Safeguarding and Other Means of Reducing Risk
- ISO 13857 Safety of Machinery Safety Distances to Prevent Hazard Zones Being Reached by Upper and Lower Limbs

#### Movable Guard:

- ISO 14119 Safety of machinery Interlocking devices associated with guards Principles for design and selection
- ISO 14120 Safety of machinery Guards General requirements for the design and construction of fixed and movable guards
- ISO/TR 24119 Safety of machinery Evaluation of fault masking serial connection of interlocking devices associated with guards with potential free contacts
- ANSI B11.19 Performance Criteria for Safeguarding

#### F. Protective Devices

- Two-Hand Control (THC); EN 574+A1
- Emergency Stop; EN ISO 13850, EN 60204-1, ISO 13850
- Interlocking Devices Associated with Guards; ISO 14119

#### G. Risk Assessment

- ISO 12100 Safety of machinery General principles for design Risk assessment and risk reduction
- ISO/TR 14121-2 Safety of machinery Risk assessment Part 2: Practical guidance and examples of methods
- ANSI B11.0-2020 Safety of Machinery

#### H. Safety Distances

• ISO 13855 Safe Distance Calculations Safety of Machinery – Position of Safeguards with Respect to the Approach speed of Parts of the Human Body

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- ISO 13857 Safety of machinery Safety distances to prevent hazard zones being reached by upper and lower limbs
- ANSI B11.19 Performance Criteria for Safeguarding, Annex D Safety Distance

#### 2.2 TEC Standards

- TEC-124-90 Guidance to the EU Machine Directive 2006/42/EC
- TEC-124-98 New Custom-Built Machines & New Custom-Built Assembly Machines
- <u>TEC-124-101</u> Control of Hazardous Energy (LOTO)
- TEC-124-160024 Waiver exception form

#### 2.3 TE Forms

- FORM 6260 Machinery Safety Risk Assessment
- FORM 6248 Machinery Safety Requirement Specification (SRS)
- FORM 6251 Machinery Safety SISTEMA lab document
- FORM 6252 Machinery Safety Validation form (hard guarding & safety devices)
- Form 6253 Machine Guarding Priority Assessment

#### 2.4 Pneumatic Resources:

These are informational resources to be used at your discretion.

- ROSS Controls Fluid Power Machinery Safety Guidebook
- Aventics Application of EN ISO 13849-1 in electro-pneumatic control systems.

#### 2.5 Other References

TEC-407-160180 – Molding Safety Handbook

#### 3 Definitions

Table 1: Definitions

Name	Definition
Alternative Methods (Measures)	A means of controlling hazardous energy (other than energy isolation) to reduce risk to an acceptable level.
ANSI Z244.1 performed as part of a regular, basic course of procedure Routine	
ANSI Z244.1 Repetitive	repeated regularly as part of the production process or cycle
ANSI Z244.1 Integral	inherent to, and be performed as part of, the production process
Actuator	The device which activates the interlock, a separate part of an interlocking device which transmit state of guard to the controller/actuating system.

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Anti-Trip/Non- Repeat	Function of operating control switches or buttons that don't allow accidental, unintended, or continuous activation of the machine.	
Assembly Machine	A machine that advances components towards a final product by assembly, adhesion, marking or testing. For use and understanding in this specification assembly machines are usually designed and built (customized) by or for TE. They generally are more complex in design and function; they may perform multiple and varied assembly steps. have software operated controls; and include one or more access doors that can be easily or routinely opened during production.	
Authorized Person	A person who is qualified to remove a machine safeguard component only after Lock out Tag out (LOTO) has been applied, and the Machine/Equipment is in a Zero energy state. Shall comply with the TEC-124-101 Protection against hazardous energy Lock out Tag out, shall be completed, signed/issued by the site or BU which adds the confirmation that Lock out Tag out has been applied, and that the machinery is in a Zero energy source state.	
B10d	a number provided by safety hardware manufacturers which represents the testing data of the hardware when 10% of the tested components failed to a dangerous state.	
Blocks	This document uses the term BLOCK as defined by SISTEMA. Safety devices that are mechanical (dry contacts) and fail based on number of operations (Nop). The manufacturer will provide B10d data for mechanical devices.	
Category	Classification of safety-related parts of a control system in respect of their resistance to faults and their subsequent behavior in a fault condition. This is achieved by the structural arrangement of the parts, fault detection and/or by their reliability. Reference ISO 13849-1.	
CEFS	Certified Expert in Functional Safety. This refers to a specific certification from TUV Nord.	
CIP Safety	Safety over Ethernet. Safety devices are controlled over a safety rated ethernet network.	
Collaborative Robot	A robot that is purposely designed to work in a collaborative workspace near a person.	
CMSE	Certified Machinery Safety Expert. This refers to a specific certification from TUV Nord.	
Devices	Other safeguarding equipment other than physical guarding such as light curtains, interlocks, pressure sensitive mats, area laser curtains, etc.	
Diagnostic Coverage (DC)	A measure of the effectiveness of diagnostics, which may be determined as the ratio between the failure rate of detected dangerous failures and the failure rate of total dangerous failures (None 0 to 59%; Low 60 to 89%; Medium 90 to 98%; High 99 to 100%.)	
Effective Protection	Effective protection has been achieved when the risk reduction measure identified in a risk assessment has been properly designed, installed, and validated. If the risk reduction includes engineering controls – devices then the PL of the safety function must meet or exceed the required Performance Level(PLr) determined by the risk assessment.	
Engineering Controls	guards or devices part of a safety function used to reduce risk	
Functional Safety	focuses on the reliability and performance of safety functions to prevent accidents and protect people. Functional Safety is achieved through the design and implementation of	

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	and the formation at the toward and side and suppose a suitable and the same authorist ICO			
	safety functions that meet specific performance criteria, such as those outlined in ISO 13849.			
Functional Safety Systems	Functional safety is the part of the overall safety of a system or piece of equipment that depends on automatic protection operating correctly in response to its inputs or failure in a predictable manner (fail-safe). The automatic protection system shall be designed to properly handle likely human errors, systematic errors, hardware failures and operational/environmental stress.			
Hazard Assessment	An assessment that is typically performed by 1-2 people and is not task/hazard based, but is hazard based only. Maintenance or non-routine tasks that are performed in the hazard area with power on are still analyzed at the task level. A hazard assessment is NOT a risk assessment.			
Integrator	Also referred to as an automation integrator or control systems integrator. Is a company or engineering firm that specializes in the design and implementation of custom automated machinery and manufacturing automation equipment for industrial and manufacturing systems.			
Interlocking Device	Mechanical, electrical or any type of device whose primary purpose is to prevent the operation of hazardous machine functions under specific conditions such as an open door or machine guard.			
Interlocking	(According to EN ISO 14 119:2013)			
Devices Description	<ul> <li>Type 1: Interlocking device with mechanically actuated position switch with uncoded actuator.</li> </ul>			
	<ul> <li>Type 2: Interlocking device with mechanically actuated position switch with coded actuator.</li> </ul>			
	<ul> <li>Type 3: Interlocking device with non-contact actuated position switch with uncoded actuator.</li> </ul>			
	<ul> <li>Type 4: Interlocking device with non-contact actuated position switch with coded actuator.</li> </ul>			
Interlocks	Safety interlock devices: interlock an electrical, mechanical, or other type of device designed to prevent the operation of dangerous machinery functions.			
Machine Guarding	A physical barrier that prevents entry by the operator into the point of operation, pinch or nip point, moving parts, or another machine hazard; can be fixed, interlocked, adjustable, or self-adjusting. A machine guard is part of a safeguarding system.			
Machine Hazard	Sufficient energy (mechanical, electrical, light, heat, chemical, stored or potential, radiation, sharp surfaces/tooling. etc.) to cause harm to a person.			
Machine Safeguarding	One or more methods including physical machine guards, devices, tools, and practices used to keep employees safe from machine hazards.			
Machine Shop- Type  Machines that are typically found in a machine shop, but may also be used in areas such as the shop floor, including but not limited to lathes, drill presses, grinders, milling machines, circular saws, band saws, wire EDM machines, etc				
Modify	Changing the original purpose, function, or capacity of the machine by design or construction.			
Non-Detachable Fixing	prevention of dismantling or re-positioning of the element of the interlocking device (e.g., welding, one-way screw, riveting) or security fixings.			

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Operating Area of the Machine	The unprotected space inside of the machine safeguarding.
Performance Levels	are defined in detail in ISO13849-1. PL is a measure of a safety functions reliability measured in PFH (Probability of Failure per Hour). Performance Levels are a combination of Categories, MTTFd (Mean Time to Dangerous Failure), and DC (Diagnostic Coverage = monitoring). They are designated as PLa, PLb, PLc, PLd, or PLe with PLe being the hazard with the highest risk.
PFHd	Probability of Dangerous Failure per Hour. A number provided by safety hardware manufacturers which represents the testing data or non-mechanical hardware.
PLC	A programmable logic controller that is either "standard" non-safety rated or is a safety programmable logic controller.
Point-of-Operation	The part of a machine that has direct contact on the part or piece being manufactured. Actions may include stamping, molding, cutting, punching, welding, sawing, forming, riveting, transferring, etc.
Qualified TE Personnel	Refers to either a TE employee or an authorized third-party representing TE, who possesses the technical expertise to understand and interpret this document for the purpose of verifying a machine's compliance. For example, a machinery safety TUV Certified TE employee.
Rebuilding / Reconstruction / Refurbish	Restoring the machine to its original design, purpose, capacity and function.
Reconfigure	A machine whose layout is different from the original configuration
Relocate:	To move a machine to a different location with no change to operation, process, equipment, arrangement, or risk reduction measures.
Remanufacture	Modification of a machine by replacing worn-out or failed components with new or used parts, resulting in different machine specifications
Repair	To restore a machine by replacing a part or putting together that which is broken without altering its original purpose, function, capacity, operation or risk reduction measures.
Restricted Space (robot)	Defined space established by installation of limiting devices which minimize the total distance a robot can travel.
Risk Assessment	A team-based task / hazard pair assessment of a machine whose goal is to reduce risk to an acceptable level. This considers all machine modes, as well as tasks performed by anybody who interacts with the machine – operators, maintenance, set-up, thread-up, cleaning, passer-by, etc.
Robot Maximum Space	The maximum reach of robot and end effector
Robot Safeguarded Space	The area inside perimeter guarding
Robot Operating Space	The space required by the tasks of the robot
Robot Restricted Space	The space restricted by limiting devices such as mechanical limiting devices or soft axis limiting.
Robot Soft Axis Limiting Inputs	Safety rated robot controller inputs which can be used to choose the Soft Axis Limiting speed cap using external safety devices such as safety light curtains and safety laser scanners

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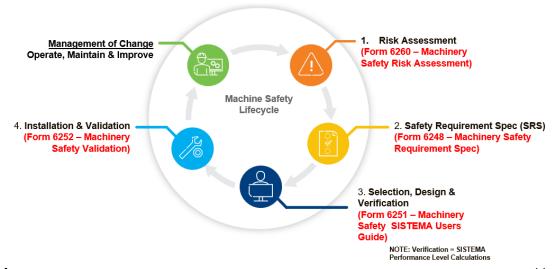
Robot Soft Axis Limiting Outputs	Safety rated robot controller outputs which can be used to stop external devices such as welders, end effectors, material handling, etc.
Safety Logic Device	Monitors/controls safety components and devices. Include safety relays, programmable safety relays, or safety PLC's.
Safety Function	a combination of INPUT – LOGIC – OUTPUT devices whose purpose is to protect a person.
SISTEMA	Software that calculates the performance level of safety functions. Free software published by DGUV.
Subsystem Device	This document uses the term SUBSYSTEM as defined by SISTEMA. Safety devices that are not mechanical and do NOT fail based on the number of operations. The manufacturer will provide PFHd or PL of this device.
Surface Grinder	A machine tool used to provide precision ground surfaces, either to a critical size or for the surface finish.
T10d	a number which represents the first expected dangerous failure of a device. ISO13849 asks to design for a T10d or 20 years. T10d = B10d/Nop. Units are years. Nop = number of operations per year of a device.
Type C Standard	A standard written for a specific machine type. If the content of a type C standard differs from this document, then they type C content takes precedence. For example, robots, presses, and molding all have type C standards.
Vertical Milling Machine	A single machine that usually holds and operates one milling tool at a time in a vertical position. While the tool travels on one vertical axis the bed that holds the part can move on multiple horizontal planes. Bridgeport is a manufacturer of vertical milling machines.

# 4 Functional Safety Requirements

## 4.1 Machinery Safety Lifecycle & Documentation

The machinery safety lifecycle shown below in Figure 1 shall be followed when implementing and documenting functional safety solutions at TE.

Figure 1: Machinery Safety Life Cycle.



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#### 4.2 Risk Assessment

Risk assessment shall use TE Form  $\underline{6260}$  or equivalent. The risk assessment process shall follow procedures as outlined in either ANSI B11.0 or ISO 12100.

The risk assessment shall include:

- Must follow the risk assessment process outlined in Figure 2 below.
- Must be task/hazard based
- Must consider all machine modes and personnel interfacing with the machine
- The scoring method must demonstrate that risk was reduced to an acceptable level
- Must produce a required Performance Level (PLr) per ISO13849 when appropriate.

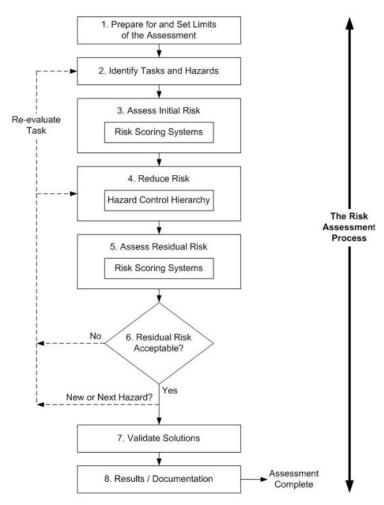


Figure 2: Risk Assessment Process.

## **4.2.1** Define the Limits of the Machine

Risk Assessments shall define the limits of the machine and shall include:

• Manufacturer, Model #, Serial Number, Manufacture Date, Location,

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- Product: Final product being produced, Product Input and how is it delivered to the machine, Product Output and how is it removed from the machine, Cycle Time or Production Rate
- Speeds, Pressures, Forces
- Energy sources: (Electric, Hydraulic, Pneumatic, Vacuum, Steam, Water, etc.)
- Environment: Temperature, humidity, elevation, etc.
- Accident history

#### 4.2.2 Escape of Trapped Persons

Risk assessments SHALL consider the possibility that a person gets trapped inside of a machine when a safety function is exercised. Consideration shall be given as to how to remove the trapped person from the machine when an E-Stop or any other safety function is activated. The release of trapped people may result in additional safety functions being defined or existing safety functions being bypassed.

#### 4.2.3 Changes to Existing Machines

## Repaired, Rebuilt, or Refurbished

If a machine is being Repaired, Rebuilt, or Refurbished utilizing components that DO change the function of the component or the safety performance of the machine the risk assessment shall be updated. The procedures outlined in this document shall be followed.

#### **Reconfigure / Relocated**

If an existing machine is being relocated or the layout is reconfigured, then the risk assessment shall be updated for any hazards created by the changes. The procedures outlined in this document shall be followed.

#### **Modify or Remanufacture**

If an existing machine is being modified or remanufactured, then the risk assessment shall be updated for any hazards created by the changes. The procedures outlined in this document shall be followed.



**NOTE:** Reference section 4.8 for more details on the above requirements.

#### 4.3 Risk Reduction

The purpose of a risk assessment is to reduce risk to an acceptable level. Follow risk reduction guidelines in ANSI B11.19 for reference.

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	Classification	Risk Reduction Measures	Examples	Influence on Risk Factors
Most Preferred	Inherently Safe by Design	Design Out (Elimination or Substitution)	eliminate pinch points (increase clearance)     intrinsically safe (energy containment)     automated material handling (robots, conveyors, etc.)     redesign the process to eliminate or reduce human interaction     reduce force, speed, etc. through selection of inherently safe components     substitute less hazardous chemicals	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 avoiding or limiting harm, depending on which method of substitution is applied
	Engineering Controls	Guards, Control Functions and Devices	guards     interlock devices     presence sensing devices (light curtains, safety mats, area scanners, etc.)     two-hand control and two-hand trip devices     alternative methods to control hazardous energy besides lockout (an administrative control)	greatest impact on the probability of harm (occurrence of hazardous events under certain circumstances)     minimal if any impact on the severity of harm
	Administrative Controls	Awareness Means	lights, beacons, and strobes     computer warnings     signs and labels     beepers, horns, and sirens, etc.	potential impact on the probability of harm (avoidance)     no impact on the severity of harm
		Information for Use (Training and Procedures)	safe work procedures     training	potential impact on the probability of harm (avoidance and/or exposure)     no impact on the severity of harm
7		Administrative Safeguarding Methods	safe-holding safeguarding method	potential impact on the probability of harm
		Supervision Control of	supervisory control of configurable elements	(avoidance and/or occurrence)  • no impact on the severity of
V		Hazardous Energy	lockout / tagout	harm
Least Preferred		Tools	workholding equipment     hand tools	potential impact on the probability of harm (avoidance and/or occurrence)     potential impact on the severity of harm
		Personal Protective Equipment (PPE)	safety glasses and face shields     ear plugs     gloves     protective footwear     respirators	potential impact on the probability of harm (avoidance)     potential impact on the severity of harm

Table 2: Hierarchy of Controls with Machinery Examples

## 4.3.1 Acceptable Risk

The TE Connectivity definition is defined as NEGLIGIBLE. This is a residual risk score of Negligible or Low.

## FOR TASKS REQUIRED OF THE OPERATOR:

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If Negligible cannot be reached and a score results in a "Low but Relevant" area, then TE will allow "Low but Relevant" to be acceptable if another risk reduction measure has been implemented such as engineering controls or awareness means, PPE, etc. Administrative controls by itself could be the only risk reduction measure applied.

If the residual risk is anything other than Negligible or Low, then alternative methods did not provide effective protection and LOTO shall be used.

# FOR TASKS REQUIRED OF NON-OPERATORS such as Maintenance or Non-Routine tasks:

If power is required to perform the task and Negligible or Low cannot be achieved, then the person performing the work shall be certified and trained to perform the task. Alternative Methods still need to be considered and implemented if the risk can be reduced.



**NOTE:** Any task with Medium or higher residual risk shall be disclosed to TE and is required to be reviewed by Qualified TE Personnel.

## 4.4 Safety Requirement Specification (SRS):

Use TE FORM 6248 Safety Requirement Specification for SRS documentation or equivalent. An SRS is a sequence of operation for a safety function.

This is a highly recommended document but not a required document for new machines from external suppliers. It is required for machines built by TE for use in a TE facility as well as existing machine upgrades or modifications.

## 4.5 Verification (SISTEMA)

SISTEMA software or equivalent shall be used for Verification and PL calculations. SISTEMA software is preferred.

Verification must be completed by the machine supplier or integrator pre-validation phase and supporting documents such as SISTEMA files, safety control system schematics or electrical drawing package, and BOM's shall be provided for review and acceptance.

A Qualified TE Personnel shall review the accuracy of the Performance Level calculation reports.

#### 4.6 Validation

Document the results within TE FORM 6252 – Machinery Safety Validation, or equivalent.

Validation shall include at a minimum:

- Hard Guarding
- All Safety Devices
- Normal Operation of all Safety Functions
- Software Validation

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A validation report shall be supplied and reviewed by qualified TE personnel. Validation is required before a new machine can be placed into production for the first time at TE facilities. Validation is completed after installation in a TE facility but before a machine is placed into production. Validation utilizes the Risk Assessment, SRS, control schematics, and safety PLC program.

#### 4.6.1 Hard Guarding Validation

Hard guarding validation shall include:

- Inspection of material used
- Inspection for proper fasteners special tool and captured
- Reaching through opening sizes and distance from the hazard (Gotcha stick).
- Reaching over Mounting dimensions away from the hazard reaching over dimensions including total height
- Reaching under Mounting dimensions away from the hazard reaching under dimensions and minimum distances from the floor.

#### 4.6.2 Safety Function Validation

Each safety function shall be tested and results documented to ensure the correct sequence of operation of each safety function on the machine. Test each safety function to ensure all the safety related outputs respond appropriately to their corresponding safety related inputs.

#### 4.6.3 Device Level Validation

Each device included in a safety function shall be validated to ensure they are mounted correctly and respond appropriately to the faults they were designed to detect.

Validation procedures may differ based on the type of device and the safety function Category Level.

#### 4.6.4 Safety Software Programming Validation

Safety programming shall be validated and to ensure proper operation and fault detection. Tests performed and results shall be included in the validation document.

#### 4.7 PL and Category Requirements

New custom-built machines and new custom-built assembly machines must meet the PL requirements outlined in TEC-124-98.

All other TE machines must meet the Performance Level or Category requirements outlined below and in section 4.8.

The Category requirements for each required Performance Level are listed below in order of preference.. The MTTFd and DC requirements per ISO13849-1 shall be met.

If PLr = PLe

- Design according to relevant standards and ISO13849-1.
- All PLe hazards and safety functions shall be disclosed to TE and are automatically required to be reviewed by a TUV certified TE employee or equivalent.

If PLr = PLd

- Preferred: Category 3 circuit structure.
- Preferred: Category 2 circuit structure with single input and the test channel output device is also safety rated and stops the hazard. This is essentially a Category 3 with a single input channel.

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• Allowed: Category 2 circuit structure in which the test channel output monitoring device is NOT safety rated or monitored and stops the hazard.

#### If PLr = PLc

- Preferred: Category 2 circuit structure with single input and the test channel monitoring output device is also safety rated and also stops the hazard. This is essentially a Category 3 with a single input channel.
- Preferred: Category 2 circuit structure in which the test channel output monitoring device is NOT safety rated or monitored and stops the hazard.
- Allowed: Category 2 circuit structure in which the test channel output device is not capable of stopping the hazard but instead provides a warning.
- NOT ALLOWED: Category 1 circuit structure. Per ISO13849-1.



**NOTE:** Any solution implemented that is not Preferred shall be disclosed to TE and is required to be reviewed by a qualified person. The MTTFd and DC requirements of each PL shall be met.

#### 4.8 New Machines or Existing Machine Modifications, Transfers, or Relocations

When an existing machine is modified, transferred, relocated, or reconfigured (internally within the same facility or to another facility), regardless of the extent of the modifications, a risk assessment shall be completed or reviewed for any new hazards. This can be a simple review or a complete assessment, depending on the scale of modification. However, each such machine shall follow a formal process, and the results of the risk assessment shall be documented and suitable risk reduction measures implemented.

See flow chart below for requirements.

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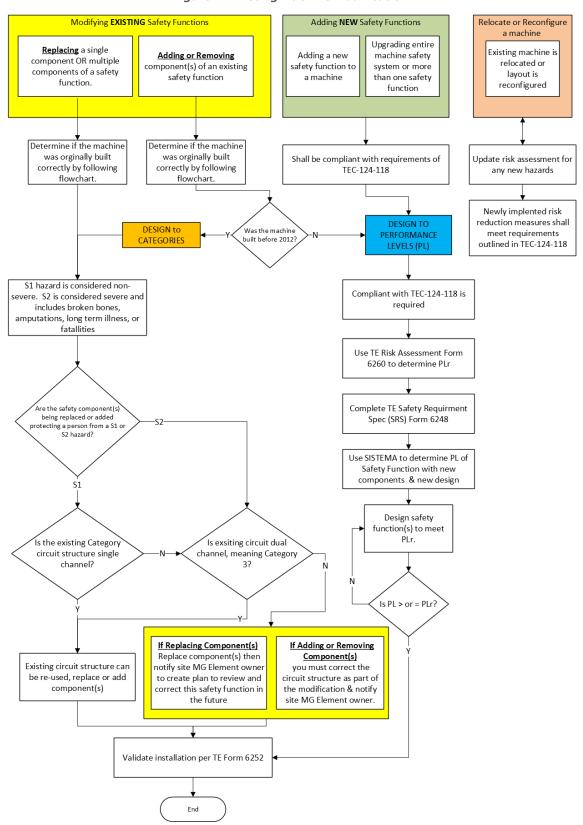


Figure 4: Existing Machine Modification

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#### 4.8.1 New Custom-Built Machines

Custom-built machines and custom-built <u>assembly machines</u> must also meet the additional requirements in TEC-124-98. Custom-built machines (TE built or externally built) require design reviews and safety documentation reviews as part of the machine acceptance and risk assessment process:

- During the mechanical design concept or after the mechanical design concepts are completed whichever is more practicable
- Upon completion of the electrical design
- After machine build is complete at machine builder location: OEM / Integrator location.

TE Connectivity requires risk assessments for all new custom-built production machines entering TE Connectivity facilities. Machine suppliers (OEM, integrator, or internally built) shall provide at a minimum these (three) machinery safety lifecycle documents including risk assessment, SISTEMA verification reports, and completed validations. The SRS is a preferred document but not required. These document formats may differ by supplier and in some instances may be combined. For example, SRS and Validation are often combined. Qualified TE Personnel along with plant EHS will review the machinery safety lifecycle documents prior to the equipment being placed into production at TE. The documents shall be delivered to Manufacturing Engineering Lead or Operations Manager. The only document where an exception can be granted is for the SRS.

TE Connectivity will complete its own facilities "as installed" risk assessment to identify any additional risks introduced by the new environment, layout, and integration of auxiliary equipment such as product input and output.

#### 4.8.2 Off-the Shelf, "Product or Catalog" Type Machines

This specification does apply to Off the Shelf or Catalog Machines to ensure the machine is safe for our employees to operator and maintain. Off the shelf machines are still subject to standards required by law such as UL or CE. TE will accept the safety documentation "as delivered" with these machines and the safety documentation shall be reviewed by Qualified TE Personnel. If safety documentation is not available, then a safety review of the machine shall be conducted by Qualified TE Personnel prior to machine being placed in production.

#### 4.8.3 Safety Device Replacement

When safety devices require replacement, follow the Safety Device Replacement Hardware Table 4 below for the Machinery Safety Lifecycle documentation update requirements.

Existing machines with single channel input devices (Gate switches, E-stops, etc...) may be re-used if they meet the PL and Category requirements outlined in this document.

For ALL mechanical dry contact safety devices:

- When PLr = PLc or PLd, the table below shall be followed for wiring mechanical dry contact type devices in series.
- When PLr = PLe, no mechanical dry contact type devices shall be wired in series.

E-stops shall be considered infrequently used.

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Table 3: Safet	v Device Replacement	Hardware
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Note: frequently used for this table is defined as  $\geq$  once per hour.

Number of frequently used mechanical devices	Number of devices wired in series	Diagnostic Coverage
	2 to 4	(Medium) 90% <u>&lt;</u> DC < 99%
0	5 to 30	(Low) 60% <u>&lt;</u> DC < 90%
	>30	(None) < 60%
	1	(Medium) 90% <u>&lt;</u> DC < 99%
1	2 to 4	(Low) 60% <u>&lt;</u> DC < 90%
	<u>&gt;</u> 5	(None) < 60%
>1	<u>&gt; 0</u>	(None) < 60%

# **5** Engineering Controls

Engineering controls is a term meaning guards or devices which are part of a safety function used to reduce risk and protect a person.

#### **5.1** Engineering Controls - Guards:

The dimensions for reaching over, reaching under, and reaching through guarding from ANSI B11.19 or ISO 13855 shall be followed.

New perimeter guarding shall be designed to a maximum distance of 180mm (7.0") from the floor. Existing perimeter guarding is allowed to be no more than 300mm or (approx. 12") from the floor. Lower heights may be required based on location of hazards. Perimeter guarding shall meet minimum height requirement of 1400mm (55"). Taller heights may be required based on "reaching over" tables.

Guarding shall be securely anchored to the machine or floor. (employees shall not be able to easily remove or tamper with the safeguard). If the guards are fixed, they shall be affixed such that unique tools are required for removal. Fixed guard fasteners shall be captive to the guard.

New guards made of perforated material like mesh guards shall be painted black to allow clearer viewing of machines. Existing machine guarding is not required to be changed to black.

Machine guarding doors, panels, frames, and Safety devices (Interlocks, Light curtains, etc.) shall be constructed and set in place with fasteners that require a unique tool to remove.

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- Unique means: fixing which are classified as Tamper proof i.e., needing a unique tool to undertake removal. Flat / Phillips / Cross / Hex / Allen-Heads are NOT classified as being unique.
- Retrofitting to meet this requirement on existing machines shall occur before or at the next
  time the component is removed for replacement, servicing (Total Predictive Maintenance TPM),
  or repair. For hard guarding, a minimum of two unique fasteners are required per side. For
  example, a square shaped fixed guard panel would require eight total unique fasteners, two
  per side.
- Unique security fixings removal tools must be restricted onsite and only used by authorized employees.

The distance to machine hazards or openings in guarding shall permit material passage, machine adjustment, heat dissipation, ventilation, etc. but shall be small enough to prevent reaching by operators into hazardous machine conditions.

#### 5.2 Engineering Control – Movable Guards & Gates:

Moveable guards shall remain attached to the machine when opened.

Moveable guards shall be monitored by an interlocking safety rated device. Interlocking does not mean locking.

Whole-body entry gates shall be designed to prevent a single person from being able to enter and close the gate interlock, thereby isolating themselves within the hazardous area.

Interlocking and locking switches shall be subsystem type devices (non-mechanical) whenever possible. Such as RFID coded switches with solid state outputs.

The use of an interlocked guard vs a lockable guard shall be determined with a safe distance calculation.

Interlocks shall be of the type that are not easily broken, bypassed, or defeated, and shall function such that all hazardous energy present to the worker is controlled and/or dissipated.

ISO14119 and ISO TR 24119 shall be followed for measures against defeating interlocking devices.

## **5.3** Engineering Controls – Devices:

Order of preference for safety component hardware:

- FIRST: Subsystem devices. Non-mechanical solid state (Subsystem) type devices: devices classified as subsystems in SISTEMA. RFID for example.
- SECOND: Mechanical devices with dry contacts. (Block) type devices: devices classified as Blocks in SISTEMA.

#### 5.3.1 Jog Pendant

If a jog pendant is used while any safety functions are bypassed, for example, when a machine door is open or a light curtain is muted:

- The pendant shall only allow machine movement in a step-by-step function or limited-speed function. The slow speed may be dependent on application. If 5% of production speed is possible, this shall be used.
- The jog pendant shall require both hands to be on the operating controls and shall not be capable of extension into the operating area of the machine.

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#### 5.3.2 Foot Pedal

Foot pedals when used to operate machines:

- Shall only be used where the safety of both hands from the hazards of moving machine parts can be ensured. Safe distance calculations and reaching distance shall be met.
- Shall have a protective cover that prevents unintended operation or cycling of the machine.
- Shall have an anti-hold down, non-repeat function. Continuous machine function will be allowed if other alternative methods are active and protecting the person from hazards.
- Are discouraged from use when the worker can reach the unprotected point-of-operation as their intention is too free one or both hands for other use which may be hazardous to the worker.

#### 5.3.3 Light Curtains / Presence Sensing Devices

- Shall be safety rated components meeting the PLr as determined by the risk assessment.
- Shall be installed such that no body part can go under, over, or around any portion of the intended area of protection and reach the machine hazard. See ANSI B11.19 of ISO13855 for more information.
- Shall be used only if the machine cannot eject failed machine parts or product as projectiles capable of striking any person.
- Typically requires a safe distance calculation performed to determine the mounting distance from the hazard.
- It is preferred that the light curtain internal EDM (External Device Monitor) not be used. The preference is to monitor the light curtain with a safety logic device.
- Light Curtains safety functions with manual reset. Manual reset is the preferred method of control. Manual reset light curtain safety functions must have a start cycle that requires manual reset first, and then a separate start button to activate machine movement after the light curtain is cleared.
- Light Curtains safety functions with auto reset. If automatic reset is required due to high frequency operator part loading / unloading, then the light curtains shall continuously detect the body part in the hazard area. Automatic reset does not require human intervention to initiate the reset function. Automatic reset shall not be used for whole body access applications.

## 5.3.4 Safety Logic Device

A safety logic device can be a safety relay, programmable safety relay, or a safety rated PLC. The Performance Level of the safety logic device shall meet the PLr as determined by the risk assessment.

## 5.3.5 HMI requirements - Safety Screens

These requirements are for new custom-built machines, new custom-built assembly machines, or any existing machine that is upgraded when the upgrade includes a Safety PLC and an HMI.

Engineering Controls – Mechanical Safety Devices: Screens shall include accumulated cycle counts for all mechanical safety devices. Both the total accumulated cycles and the estimated cycle used for PL calculations shall be displayed. The current cycle run rate can be used to extrapolate an estimated annual usage for Nop (Number of Operations per year). The annual usage cycles shall be used to calculate an actual MTTFd and T10d for that device. When the device has approached 95% of the T10d number an alarm shall be produced signifying device

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needs to be replaced. Once the actual T10d time has expired an HMI alarm shall be produced, and the machine shall not restart until the alarm is acknowledged. When devices are replaced, the device count shall be able to be reset from this screen.

- Engineering Controls Subsystem Solid State Devices: Screens shall include the elapsed time
  from machine installation for subsystem type devices. . When the device reaches 19 years and
  11 months an alarm shall be produced signifying device needs to be replaced. When devices
  are replaced, this time shall be able to be reset from this screen. When the accumulated time
  for any device exceeds 20 years an HMI alarm shall be produced, and the machine shall not
  restart until the alarm is acknowledged.
- <u>Device testing / cycling:</u> Per ISO14119, PLd safety functions are required to be cycled a minimum of once per year while PLe safety functions are required to be cycled a minimum of once per month. The safety PLC program shall ensure safety functions are cycled within these time frames. If safety functions have not been cycled within these time frames, then an alarm shall be displayed on an HMI notifying the operator of the tasks required to exercise the safety function with visual guidance as to their location. This alarm is not required to immediately stop the machine, but once stopped, the machine shall not be able to be restarted until the safety function has been cycled.
- <u>Performance Level</u>: Screens shall include the PLr of each safety function. Screens shall also include the actual PL based on the accumulated Nop for mechanical devices. If safety function does not include any mechanical devices, then the SISTEMA calculated PL can be displayed. The PLr for each safety function shall be displayed as well.
- Screens shall display the safety signature of the safety logic device.

#### 5.3.6 Machinery Emergency Stop (E-Stop) Requirements

E-Stops are discussed and governed by many different standards including NFPA 79, ANSI B11.19, ISO13849-1, and IEC60204.

After an emergency stop has been actuated, the sequence of actions necessary to resume operation shall be as follows:

- Pull or twist to release the emergency stop pushbuttons that have been actuated or restore the tension on pull cord switches that have been actuated. This action shall not be considered a safety function reset.
- Press the safety reset push button to reset the emergency stop safety function.
- When ready, press the machine control start push-button(s) to resume operation.

Self-monitored contact blocks shall be used in designs where this is mechanically possible.

All E-Stops at shall meet the below minimum requirements:

• E-stop safety functions shall be designed to meet the highest PLr of all hazards stopped when the E-stop is activated. If a machine contains PLe rated hazards, the E-stop shall be designed to meet a maximum of PLd.

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- For E-stops wired in series, they shall be considered infrequently used see Table 3 in section 4.8.3.
- E-Stops are typically global and stop all hazards. However, if an E-Stop is "zoned" and has a specific span of control then the span of control shall be defined and clearly labeled at the button.
- Shall be red with a yellow background as required by relevant safety standards.
- Initiated by a single human action (i.e. only manual operation)
- Operational at all times and overrides all other functions and operations in all operating modes
  of the machine.
- Shall cease all hazardous motion by placing all energy sources and hazards in a safe state and dissipating any stored or potential hazardous energy.
- E-Stop shall be used for emergency shut down and shall not be used to shutdown equipment during standard operation.
- E-Stop shall stay engaged until manually reset.
- E-Stop is an additional protective measure it is not and shall not be used as a substitution for proper safeguarding of the equipment.
- E-Stop shall not impair the effectiveness of other safety devices.
- E-Stop shall be installed at each operator control station and at other locations, as determined by Machine risk assessment. Typical E-Stop locations: near PLe rated hazards, near areas where operator or maintenance tasks are routinely performed.
- Installed protective covers or shrouds over E-Stops to prevent inadvertent actuation are NOT allowed.
- E-Stop shall be installed in way to avoid accidental activation by operator and same time be easily accessible from operation position.
- The escape of trapped people shall be considered in Risk Assessments when machines are in an E-Stopped state.

#### 5.3.7 Reset

The rest function shall be initiated with a physical blue push button. Special exceptions to this must be granted by TE.

The reset button shall be located outside all hazard areas. The entire hazard area and all hazard areas within the zones of control of the safety functions being reset by the reset button shall be visible from the rest push button location. If this is not possible, additional measures shall be taken to ensure no people are in the hazard area prior to safety systems accepting the reset signal.

The reset shall take place on the "falling edge" of the button push. This means when the button is released.

Resets shall meet the following requirements (per ISO13849):

 Be provided through a separate and manually operated device that is separate from the start command

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- Only be achieved if all affected safety functions and safeguards are operational
- Not initiate motion or a hazardous situation by itself
- Be initiated by intended action
- Enable the control system to accept a separate start command, and
- only be accepted by monitored signal change, in order to avoid foreseeable misuse.

It is mandatory that all safety functions require a reset command prior to the equipment re-starting.



**NOTE:** This means that when an interlock, light-curtain, emergency stop, or other safety devices are activated, prior to the machine restarting the reset button must be pushed.

## 5.4 Engineering Controls – Fluid Power:

Safety functions which include fluid power (pneumatic & hydraulic) components shall meet the Performance Level or Category requirements outlined in this document.

Both electric and air/hydraulic energy sources shall be considered when designing fluid power safety.

The re-application of air is an event that shall not cause unexpected motion or cause damage to the machine. Flow controls and soft starts may be necessary at the system level or at the specific cylinder location.

## 5.4.1 Trapped Air (Residual Pressure)

- A. Valves with a 5/2 configuration are preferred.
- B. Any situation that creates trapped air shall be labeled with precautionary label about residual air pressure and must include a way to release air pressure (manual relief). This additional hazard must be indicated in the machine's documentation (in a list) and accounted for in the risk assessment.
- C. Air pressure release valves must include the ability to be actuated without tools and labeled as such.
- D. Vertical machine functions that can cause a hazard when the energy source is removed shall include additional risk reduction measures.
- E. Recommended type of label from ISO 7000 Ref. No. 1320

Figure 4: Type of Label



This symbol alerts operators that pieces of the machine are still under pressure.

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#### 5.4.2 Air Reservoirs

- A. Air tanks used to store additional volume of air (Boosters) shall have a manual air release and must be labeled with precautionary statements.
- B. Air tanks may be used when it is determined pneumatic hazard movement is required for the purpose of escaped of trapped persons under an E-stop condition. This pneumatic circuit would be part of a safety function and therefore is subject to performance level requirements.
- C. Boosters must also have redundant and monitored valves to block downstream pressure when the tank does not bleed off pressure while the doors are opened.
- D. Downstream pressure must be bled off.
- E. Components used for booster systems must be designed to meet the extra pressure needs.

#### 5.4.3 Handheld Air Hoses

#### **Hand-Held**

- A. Air guns must be safety rated air guns which meet local, regional, or national safety noise and pressure requirements.
- B. Air nozzles must be of the safety type that directs trapped air to the side or away from the tip when the tip is blocked.
- C. If an air gun is not safety rated, the pressure must be limited at the nozzle tip to not exceed 30 PSI (2bar).
- D. Not to be used for personal or area cleaning without adequate PPE.
- E. Be used only in a manner to not project hazardous air pressure or particle in the direction of any person.

#### **Machine Connections**

Hose and hose connections used for conducting compressed air to utilization equipment shall be designed for the pressure and service to which they are subjected. Worm gear clamps are not designed for this type of application and shall not be used. Example of compliant clamps are crimped fittings or push lock.

#### 5.5 Machine Modes

#### 5.5.1 Automatic Mode

To run automatic mode all doors shall be closed and all safety devices uninterrupted. Any opening of doors or interruption of a safety function (ex: light curtain) while hazards are in motion shall initiate an emergency stop.

#### 5.5.2 Other Modes

- A. General requirements:
  - All efforts must be taken to eliminate tasks defined in the risk assessment as PLe.
  - Any mode requiring proximity to hazardous motion that is typically inside the machine safeguards shall include additional engineering controls safeguarding solutions to protect

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- that person from harm. For example: two hand controls, hold-to-run, enabling device, limiting range of motion, limiting speed, limiting torque, etc..
- These special modes allowing proximity to hazardous motion that is typically inside the machine safeguards shall only be selected via a mode switch offering local control. For example, a keyed selector switch.

#### 5.6 Machine Shop Equipment

Machine shop-type equipment requires safeguarding sufficient to protect the worker from unintended contact with the machine hazard. Machine shop equipment should be in a secure area or room and only accessible to qualified personnel. These machines require guarding up to local regulation only.

All machine shop-type equipment shall be capable of holding the part to be cut, milled, ground, drilled, polished, or formed without the operator needing to hold the part.

Bridgeport-type vertical milling machines shall have either a telescoping guard covering the quill, spindle, and tool or a bed guard.

A chip guard may be used on a vertical milling machine in lieu of a telescoping or bed guard but must be large in coverage area and interlocked into the machine.

Horizontal surface grinders must include guarding that covers 210 degrees of the grinding stone.

Where an interlock is used on a door or other guard on a machine shop-type tool the interlock must not release the guard to open until the tooling has stopped all motion or has slowed to an approved safe-speed specific to the machine. Existing door or guard interlocks not compliant with this section may remain in-use until the machine is upgraded or replaced, or 3 years from the date of this specification, whichever is sooner, and if other equally protective safeguarding measures are used.

Lathes shall have interlocked chuck guards and Emergency Stops.

Drill presses and bandsaws shall have fixed, adjustable, or telescoping guards that cover the entire tool except for the minimum area of the tool required to drill or cut the material.

Circular table saws shall be guarded so that guarding covers the entire portion of the exposed blade both above and below the table except for the minimum portion required to cut the material.

#### 5.7 Assembly Machines

Reference <u>TEC-124-98</u> for New Custom-Built Machines and Custom-Built Assembly Machine requirements

#### 5.8 Robots

Machines, which include robots, shall still meet the requirements of this standard. However, robotics have their own Type C standards (ANSI RIA 15.06 OR ISO10218) which shall be followed. These standards shall be used for robot arm specific hazards but do not apply to the entire workcell.

All safety functions which include a robot as the output device <u>SHALL be designed to PLd Category 3</u>. This requirement is for ALL robots regardless of age. This requirement is for safety functions which include the robot, not for auxiliary equipment. Other hazards present in the robotic workcell can be designed as outlined in this document.

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#### 5.8.1 New Robot Systems

New robot systems typically included integrated safety features and new robot applications shall utilize the safety features integral to the robot controllers. For example:

- E-stop inputs, Fence Inputs, Soft Axis Limit Inputs
- Safe teach speeds (250mm/s)
- Safety over communication network (ethernet for example)
- Soft Axis Limiting
- Key or lockable mode switches

Full speed playback is not allowed while people are in the working space of the robot. While people are in the working space of the robot teach speed (T2) must be used.

#### 5.8.2 Older or Existing Robot Systems

Older or Existing Robot & robot controllers may not include built-in safety features. These robots can still be used in robotic applications, however, the safety features described above shall be implemented through external safety system controls. The solutions implemented shall meet or exceed the required performance level (PLr). The performance level SHALL be designed to PLd Category 3 for safety functions which include the robot. These solutions may include:

- Robot axis hard stops
- Robot axes position monitoring
- Robot auxiliary axis hard stops or monitoring
- Additional safeguards if robot does not include safe teach speed of (250mm/s)
- External motor contactors to remove power from robot controller or individual axis motors

Other non-robotic workcell hazard PLr's can be determined and mitigated as outlined in this document.

#### 5.8.3 Safe Distance

Tasks requiring the use of <u>manual high-speed mode</u> shall provide a minimum clearance of 500mm (20 inches). This clearance is required between the calculated stopping location of the hazard and areas of building, structures, perimeter guarding, utilities, other machines and equipment not specifically supporting the robot function that may cause a trapping or a pinch point.

Manual high-speed playback or automatic mode is not allowed while people are inside the restricted space.

Safe distance calculations are measured from the edge of the programmed soft axis limits or hard stop axis limits.

#### 5.8.4 Enabling Devices

All people working inside the hazard area with robot enabled, shall use an enabling device. A teach pendant with a 3-poistion switch is a valid enabling device.

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LEGEND

Robot #1

Robot #2

#### 5.8.5 Multi-Robot Systems

The Span of Control layout shall clearly define robot safeguarded, restricted, and operating space of each robot. It shall also show locations of Engineering Controls -Devices and which robots they control. This will include the Engineering Controls -Devices designations as either global or zoned.

This shall be documented in the Span of Control tab of the TE FORM 6248 SRS (Machinery Safety Requirement Spec) or equivalent. For example:

CONTROL ZONE A Machine (sorter) Machine (balancer) Machine (packager) Fixed (perimeter) Guards Interlocked Guard (closed) Interlocked Guard (open Reset Pushbuttor Emergency Stop Pushbutt CONTROL Emergency Stop Cable Pull ZONE D Presence Sensing Device CONTROL ZONE B CONTROL ZONE C

Figure 5: Example Span of Control Layout

While performing maintenance, calibration or testing on one or more of the robots in the cell while others are in manual and/or automatic mode, the robot(s) being worked on is required to be disconnected from the operation in the rest of the robot system. The site shall perform a risk assessment and create work instruction on how to have an employee safely work on this robot without being in the hazard zone(s) of any of the other robots in the robot system and determine if additional controls need to be put in place to perform these tasks.

#### 5.9 **Collaborative Workspace & Robots**

Simply because a robot is collaborative does not mean it should automatically be viewed as safe. When possible, human access to the collaborative robot's workspace should be protected and guarded. A collaborative robot shall only be allowed to operate "out in the open" with no hard guarding or engineering controls devices installed if a proper risk assessment is performed. The end effector tool shall be considered part of the collaborative robot.

Machines which include collaborative robots shall still meet the requirement of this standard. However, collaborative robotics has their own Type C standards (ANSI RIA TR R15.606, ISO15066, or ISO10218-1 & ISO10218-2) which shall be followed. These standards shall be used for robot arm specific hazards but do not have to be used for the entire workcell.

All safety functions, which include a robot arm as the output hazard device SHALL be designed to PLd <u>Category 3.</u> This requirement is for ALL collaborative robots regardless of age.

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During installation and/or modification collaborative workspace, the site shall include safety requirements for the collaborative workspace and robot(s) which shall include following as a minimum:

- Ensure adequate protective measures to always ensure the operator's safety during collaborative operation.
- During collaborative operation, the operator shall have the means to stop motion at any time by a single action (e.g. E-Stop, safety enabling device).
- Visual indicator to identify when the robot is in collaborative and non-collaborative operations.
- Established (three dimensional) limits of collaborative workspace.
- Establish access and clearance by documenting the following, proper clearance and no obstacles, accessibility for operators, access routes, and clean walk work surface areas in and around the collaborative workspace.
- Establish a list of intended and unintended contact situations based on the individual robot operation. The employee(s) shall fully understand the potential contact situations to be able to avoid and the methods for avoiding contact with the robot.
- Establish the transitions (time limits) from start and end of collaborative operation; Establish the process for the equipment to transition from collaborative to other types of operation (non-collaborative).
- If the system shall be used in non-collaborative mode, the system shall have safeguarding in place to either prevent access or a presence sending device (PSD) to sense when anyone enters the hazard zone.

The machine risk assessment for collaborative robots shall be conducted for both collaborative and if applicable, non-collaborative operation. This risk assessment shall review at a minimum the below items:

- Robot characteristics (e.g. load, speed)
- Operational Parameters for operating the robot in collaborative operation; and, during hand guided operation (safety-rated monitored speed limit, range of motion limitation(s), safety-rated soft axis (for all axis's) and space limiting)
- Contact conditions determine as to whether contact would be transient or quasistatic and the parts of the operator's body that could be affected
- Environment (e.g. Operators location with respect to proximity of the robot, orientation of the structure, location of hazards on fixtures).
- Fixture design, clamp placement and operation.
- Design and location of any manually controlled robot guiding device (e.g. accessibility, ergonomic, potential misuse).
- Process-specific hazards (e.g. temperature, ejected parts, welding splatters).

## 5.9.1 Hand Guiding Requirements

The site shall document and implement the minimum requirements for an operator using hand guiding operation to robot system in collaborative operation requirements, which shall at a minimum include:

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- Before commencing hand guided operation, the robot shall be in collaborative operation mode and achieve a safety-rated monitored stop
- Operator and all other employees that work in the area shall be outside of the hazard zone during verification of collaborative operation safety programming

Prior to being placed into production:

- The safety-rated monitored speed function, safety-rated stop function, safety-rated soft axis for all axis and space limitations shall be verified.
- The guiding safety devices ability to stop the robot shall be verified.
- The robot hand guiding device that includes an operational E-Stop function shall be verified.
- Verification of the mapping between the motion axes of the hand guiding device and the motion axes of the robot so that the mapping is clearly represented and easily understood by the operator and all area employee(s) shall occur. This shall also serve as a verification that the hand guiding operation is safe.
- The safe transition from hand guiding operation to non-collaborative mode shall be verified. This transition shall not introduce additional risk and/or unexpected motion.

Speed and separation monitoring operation requirements for collaborative operation, this is the scenario where an employee and robot can work together while they work at the same time in the same area (concurrently in the collaborative workspace). The site shall document and implement the minimum requirements for the speed and separation operation requirements, which shall at a minimum include:

- The hazardous parts of the robot system shall never get closer to the operator than the protective separation distance. The protection separation distance can be calculated based on the concepts used to create the minimum distance formula in ISO 13855 or ANSI B11.19. The protective separation distance shall be the one with the highest safety rating.
- The robot shall be programed to stop if the minimum separation distance is exceeded with all employees in the area taken into consideration. The robot may restart once the separation distance between the operator and robot has been met.
- The robot shall be equipped with safety-rated monitored speed function and a safety-rated monitored stop function.
- If operator safety is dependent on limiting the range of motion of the robot, the robot shall be equipped with safety-rated soft-axis and space limiting.
- The means to determine the relative speed and distance of the operator and robot system shall be safety-rated in accordance with the requirements in ISO 10218-2.
- If the robot is set to a constant speed limit value, the speed limit value shall be set as a safety-rated monitored speed.
- If the robot is set to a variable speed settings situation, the speed of the robot system and of the operation are used to determine the applicable value for the protective separation distance for each speed at which the robot operates.

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Power and force limiting collaborative operation. In this method of operation physical contact between the robot system and operator can occur either intentionally or unintentionally. The site shall document the minimum requirements for the power and force limiting collaborative operation requirements, which shall at a minimum include:

- The robot system shall be specifically designed for this type of operation.
- The contact situations (e.g. intended contact, incidental contact, failure modes that lead to contact) and all conditions in which these situations could occur shall be documented.
- The risk potential for such contact shall be evaluated and this risk review shall include but not limited to:
  - o Body Parts/regions that have the potential to be exposed to hazard.
  - Probability or frequency of occurrence
  - Type of contact (i.e. quasi-static or transient)
  - Speeds, forces, pressures, momentum, mechanical power, energy, etc...
- The risk reduction measures for potential contact between robots and operators shall be documented. Risk reduction shall be achieved, either through inherently safe means in the robot or through a safety-related control system, by meeting all the control requirements in the risk assessment (i.e. below threshold limit values)
- The passive and active risk reduction measures shall be documented to address the potential quasi-static and/or transient contact. Passive safety design methods address the mechanical design of the robot system. Some examples of passive safety designs include but are not limited to:
  - o Increasing contact surface area rounded edges/corners, smooth surfaces, etc.
  - Absorbing energy, extending energy transfer time or reducing impact forces padding, cushioning, deformable components, etc.
  - o Limiting moving masses

#### 5.9.2 Active Safety Design Methods

Active safety design methods address the control design of the robot system. Some examples active safety design includes but not limited to:

- Limiting forces or torques
- Limiting velocities of moving parts
- Limiting momentum, mechanical power or energy as a function of masses and velocities
- Use of safety-rated soft axis and space limiting function
- Use of safety-rated monitored stop function
- Use of sensing to anticipate or detect contact (e.g. proximity or contact detection to reduce quasi-static forces)

The robot system shall be designed to adequately reduce risks to an operator by not exceeding the applicable threshold limit values for quasi-static and/or transient contact. The threshold limit values shall be calculated based on the pain sensitivity thresholds at the human-machine interface in situations

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where such contact occurs. These threshold limits can be used to establish pressure and force limit values for various body areas as noted in ISO/TS 15066:2016(E) Annex A, Table A.1 Body model description and Table A.2 Biomechanical limits which include body model descriptions.

The power and force control limits measures shall be documented and implemented to address the potential quasi-static and/or transient contact as noted in ISO/TS 15066:2016(E) Annex A, Table A.1 Body model description and Table A.2 Biomechanical limits. These power and force control limits can include but are not limited to:

- Configure limiting threshold (e.g. forces, torques, velocities, momentum, mechanical power, axis ranges and/or space ranges)
- Limiting the speed of moving parts (e.g. robot, tooling or workpiece)
- Physical characteristics (e.g. surface area of the moving part)
- Design characteristics (e.g. robot design to avoid trapping or clamping)

#### 5.9.3 Safety Logic, Controls, Automation

All safety functions, which include a robot SHALL be designed to PLd Category 3. This requirement is for ALL robots regardless of age. This requirement is for robots only, not for auxiliary equipment. Other hazards present in the robotic workcell shall be designed as outlined in this document.

#### 5.10 Training

Training on machine specific safety requirements shall be provided. The operator and maintenance training shall address the following areas:

- Machine specific safety requirements devices and their functions.
- Understand visual warning and hazard zone identification
- Understanding of Preventative Maintenance of Safety equipment

## **6** Documentation

#### 6.1 Machine Documentation and Programming Languages

- A. Written documentation and user interface shall be supplied in both the language of the receiving location as well as English.
- B. All safety written coding shall be in English (TE Requirement).
- C. All labels shall be provided in the local language of the country where the machine is to be used.



**NOTE:** It is acceptable for pictograms to be used exclusively if explanations are given in the machine's documentation

#### 6.2 Content of Technical Documentation

The following minimum documentation shall be provided:

A. A general description of the machine.

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- B. An overall drawing of the machinery (3D PDF).
- C. Connection diagrams for all energy sources used in the machine.
- D. Bill of Material for all purchased components
- E. Safety documents shall be provided that include:
  - Risk assessment using TE template Form 6260 or equivalent.
  - Safety Requirement Specification (SRS) using TE template Form 6248 or equivalent.
    This is a preferred document, not a required document for new machines from
    external suppliers. It is required for "TE built machines for use by TE" and for existing
    machine upgrades or modifications.
  - SISTEMA or equivalent Verification for each safety function (SISTEMA native electronic file format in English and Native language)
  - Validation documents using TE template Form 6252 or equivalent. Equivalent means the validation covers at a minimum: hard guarding, safety devices, SRS, and software validation results.

#### **6.3 Documentation Exceptions**

If an OEM does not agree to deliver a copy of their safety documentation to TE, then they are required to provide the list of ANSI/ISO/IEC standards their machine is designed to as well as an in-person or virtual review of the documentation by Qualified TE Personnel. This list shall be delivered to the site EHS lead and/or the TE Project Lead

No document exceptions allowed for custom-built machines or custom-built assembly machines.



**NOTE:** Issues that may require deviation must be reviewed before the machinery is ordered or manufactured. Any changes to the machinery after it has been installed and approved must be re-approved by the facility EHS Manager to provide an additional level of review.

### 6.4 Responsibility to Issue a CE Conformity (European Economic Area Only)

A. The responsibility to issue the CE conformity for the whole process is with the party that is considered the "integrator". It is preferable that a third party be the integrator. The integrator can be a TE representative if an outside firm is not assigned this task. Although the integrator may not have made any of the components, it is the integrator's responsibility to issue the CE conformity for the whole process. The party that is the integrator must be defined before any work begins. As a result, all manufacturers of components are required to provide all necessary information to the integrator to assess risks and determine safety requirements for the whole process. This agreement is included as part of the purchase contract and any deviations need a written agreement. All parties have not completed their requirements until official approvals have been issued from TE Connectivity Engineering, the manufacturer and TE EHS. Any deviation must be documented and signed by the following TE personnel; Facility Manager, Regional Operations Leader, and Business Unit EHS Leader.

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- B. A technical file that includes the CE declaration of conformity (to include the declaration of incorporation) of machinery and/or other products incorporated into the machinery is required.
- C. The safety documentation shall be included in the technical file and shall be reviewed by a qualified TE resource prior to a new machine being placed into production in any TE facility. The minimum documents shall include risk assessment, SISTEMA native program or equivalent, and validation testing results.
- D. If TE is considered the integrator, the CE conformity certificate needs to be issued on behalf of the TE legal entity and signed by the general manager according to legal requirements. A TE engineer, assigned as a project manager, needs to assure that all steps needed to certify a machine (risk assessment, verification, etc.) are taken and documentation is provided (technical file) according to the EU machinery directive.

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# **Revision History**

Revision	Date Incorporated By		Summary of Change	
А	June 2025	Corporate EHS	Initial Issue	

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