

Aliaxis EMEA – Equipment Safety Standard Requirements

Table of Contents

Pur	pose	2
1.	Introduction:	
2.	Glossary	
3.	General Requirements:	
4.	Related documentation and regulations	
5.	Risk Assessment:	
6.	Requirements for LOTO system:	
7.	Requirements for solutions of Safety Measures, Protective Devices and Safety-Related for Control Devices	
8.	Whole-Body Entry to operating enclosures including Robotic Workplaces:	
9.	Noise protection	
10.	Maintenance	
11.	Emergency Stop	
12.	Machine points	
13.	Sites Requirements	
14.	FAT Safety Checklist & Process	
15.	Site commissioning safety checklist	
ıJ.	Site commissioning surety checking the manner of the comment of th	



Purpose

1. Introduction:

Machinery safety is an essential part of the entire Occupational safety. Improving the safety of machinery and compliance with applicable laws, regulations and standards in this area are key to the prevention of accidents and occupational diseases. This document serves as an overview of the basic safety requirements for machinery that must be met when purchasing and installing new or modifying existing machinery and equipment. The document is certainly not a list of all obligations and requirements that must be met in terms of applicable laws and standards, only draws attention to aspects of machinery safety, which Aliaxis pays close attention or requires them beyond the requirements of legislation and standards.

This procedure sets out the minimum standards to ensure workplace equipment and machinery purchased or transferred within group for use in Europe and the EMEA region meets specific legal requirements.

Supplier MUST comply that the equipment:

- Be safe when supplied
- Automatic shut off device install for hydraulic pumps in the event of fire
- Provided with declaration of conformity and user instructions
- Comply with ALL relevant EU & UK Laws, Regulations and Directives such as CE and UKCA
- Equipment name plates shall be written in the language of the destination country.
- Documentations of the equipment shall be written in English and the language of the destination country.
 - Machine/Station HMI must have as primary the language of the destination country and flexibility to change the language to other in its totality (menus, error messages, etc.)

2. Glossary

- a) Equipment: is any machinery, appliance, apparatus, tool or installation for use at work that has energized moving parts and covers any machinery sourced through the existing capex procedure, machinery transfers within group and other smaller purchases that fall into the given definition.
- b) The use of equipment: Any activity involving work equipment and includes starting, stopping, programming, setting, transporting, repairing, modifying, maintaining, servicing, and cleaning.
- c) FAT: Factory Acceptance Test, the Process to test the new Equipment at the Factory vendor/supplier to it is performing as requested and in compliance with regulations and norms, prior to shipment to the customer
- d) SAT: Site Acceptance Test, the Process to test the new Equipment at the Manufacturing Site of the customer to ensure it is as requested and in compliance with regulations and norms, and all open items or task found during the FAT have been closed.
- e) HMI: Human Machine Interface.



3. **General Requirements:**

in the purchase, production, modification, repair, etc., of machinery, steps should be taken to ensure that the equipment (in terms of safety and health at work) before putting into operation, meet the requirements of all applicable regulations and standards as well as specific requirements laid down by the local Aliaxis manufacturing plant

All newly installed, modified, or refurbished equipment must meet all EU CE and UK CA regulations and certifications at the time of power-on. It must match

- Government Regulation No. 176/2008 Coll. on technical requirements for machinery,
- Government Regulation No. 378/2001 Coll. laying down more detailed requirements for the safe operation and use of machinery, technical equipment, apparatus, and tools
- and must be issued with an EC declaration of conformity containing a declaration that the machinery complies with all relevant provisions of the relevant European Union regulations –
 - (Government Regulation No. 176/2008 Coll., or Directive 2006/42 / EC of the European Parliament and of the Council of 17 May 2006. On machinery and amending Directive 95/16 / EC (recast)
 - Directive 2009/127 / EC of the European Parliament and of the Council of 21 October 2009 amending
 Directive 2006/42 / EC as regards machinery for pesticide application.)

4. Related documentation and regulations

These include but are not limited to the following regulations and standards during project realization. It must be verified by the supplier and the site making the requisition as part of the FAT & SAT - equipment delivery:

General

- DIRECTIVE 2006/42/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast)
- ISO 12100 Safety of machinery General principles for design and risk assessment and risk reduction
- ISO 4413:2010 Hydraulic fluid power
- ISO 4414:2012 Pneumatic power
- ISO 14118:2017 Safety of Machinery Prevention of unexpected start-up
- ISO 13849-1: 2015 Safety of machinery Safety-related parts of control systems Part 1: General principles for design
- ISO 13849-2: 2012 Safety of machinery Safety-related parts of control systems Part 2: Validation
- ISO 14120:2015 Safety of machinery Guards
- ISO 14122:2016 Permanent means of Access to Machinery Part 1: Choice of Fixed Means and General Requirements of Access, Part 2: Working Platforms and Walkways, Part 3: Stairs, Stepladders and Guard-Rails
- ISO 14123:2015 Reduction of risk to health resulting from hazardous substances emitted by machinery
- ISO 13852 Safety of Machinery Safety distances to prevent danger zones being reached by upper limbs
- ISO 13853 Safety of Machinery Safety distances to prevent danger zones being reached by lower limbs
- ISO 13854:2017 Safety of Machinery Minimum gaps to avoid crushing of parts of the human body
- ISO 13855:2010 Safety of Machinery Positioning of Safeguards with respect to the approach speeds of parts of the human body

Page: 3/15



Equipment Specific

- ISO 10218-1:2011 Safety requirements for Industrial robots
- ISO 10218-2:2011 Safety requirements for Industrial robots
- ISO /TS 15066:2016 Robots and robotic devices collaborative robots
- ISO /TR 20218-1 Safety design for End-effectors
- IEC 62998 Safety-related sensors used for protection of persons
- ISO 16092 Presses "Mechanical, Pneumatics, Hydraulic"
- ISO 23125:2015 Safety Turning Machines
- ISO 20430:2020 Plastics and rubber machines Injection moulding machines -Safety Requirements
- EN 289 Safety requirements for Compression Moulding Machines
- EN 422 Safety requirements for Blow moulding machines
- EN 1114-1:2011 Safety requirements for extruder machines for plastics
- EN 1417-3:2014 Safety requirements for two roll mill machines for plastics
- EN 415-1:2014 Safety for packaging machines Part 1: Terminology and classification of packaging machines and associated equipment
- EN 415-3:2021 Safety for packaging machines Part 3: Form, fill and seal machines, fill and seal machines
- EN 415-5:2006 Safety of packaging machines Part 5: Wrapping machines
- And other

5. Risk Assessment:

The supplier must ensure adequate risk assessment of the station/machine, provide update, and submit documentation to the EHS and Engineering of (Aliaxis) for inspection and comments. If (Aliaxis) raises any comments on the assessment, the assessor must take them into account in the assessment.

When the risk assessment is conducted by the supplier, the documentation of risk assessment will be, if possible, requested from the supplier and attached to the accompanying documentation. This should be ensured in the negotiation of the contract with the supplier.

The risk assessment must also consider the following risks and hazards

Mechanical

- Trapping, pressing, squeezing, hitting, etc., limbs, body and head, etc., by moving parts
- Trapping, wrapping, hitting, etc., limbs by rotating parts
- Drop/ejection of the machined part or part of the equipment and hitting, squeezing, crushing limbs, body, and head
- Loss of stability of equipment, its tilting over and fall
- Unexpected and undesirable machine start-up (in servicing and working on the equipment)

Hydraulics

• Skin and eye contact with hydraulic oil - pressure jet - hydraulic injection

Compressed air



- Contact with compressed air air injection embolism
- Eye and skin contact: with compressed air and flying impurities and particles

Electrical energy

Contact with live parts (particularly during repairs and maintenance)

Fall from a height.

Tripping or slipping

Contact with Chemicals

Heat

- Burns from hot parts or machine parts
- Contact with leaking hot liquid or steam

Noise

Vibrations

Radiation

- UV and light from devices glare, eye damage
- Lasers glare, eye damage

Manual handling of loads - ergonomics

- Forced position
- Difficult positions
- Heavy loads weight limits for occasional
- Total physical stress
- Burden of local muscle groups

Use of cranes - fall of load

Control of eccentric loads

Release of spring tension or compression

Sharp edges and protrusions - bruises, scratches, cuts, and stabs

Vapors and gases - inhalation

Dust - inhalation

Risk of explosion

Fire, ignition

Control and grounding of static electricity/ charge

Transport means - danger of collision with traffic, impact, overrunning, control of

Presence of other persons in the workplace etc.

6. Requirements for LOTO system:

- All powered or energy/media containing the equipment must be provided with Lock-out/ tag-out functionality for easy and safe serviceability and maintenance
- The equipment must allow safe and lockable disconnection from all different sources of energy and media (electrical, pneumatic, mechanical, steam, gases, water, etc.)
- Disconnectors/isolators must be easily accessible and clearly marked and placed so that it is obvious which part of the machine and which energy they disconnect.

Page: 5/15



- Disconnectors must be included in the regular system of checks and inspections to guarantee their flawless operation
- Disconnectors must by fail safe
- LOTO disconnectors for electrical energy are to be in yellow-red colour (red rotating part on a yellow background) and should be in the OFF position to allow placement of at least three padlocks. If the machine is equipped only with the main switch disconnector, which also performs the function of LOTO disconnector, it can be in blackgrey colour. (For machines order before 06/2019, black-yellow colour is only possible)
- If the machine can be in off mode disconnectors off accumulated energy (e.g., pressurised oil or air, etc.), it must be equipped with device for safe release of these energies and unique reliable control system in order to be able to verify that energy has been released and is no longer present in the equipment (e.g., pressure gauges, pressure indicators, etc.). These elements must be included in the regular system of checks and inspections.

7. Requirements for solutions of Safety Measures, Protective Devices and Safety-Related for Control Devices.

A. If the risk assessment evaluates any hazard that can result in permanent injure, or in a similar extent that would significantly affect further life of the injured person, a technical solution (measures) should be adopted, and subsequently organizational solutions (measures) should be adopted to reduce these risks. The sum of adopted technical, organisational, and other measures must always reduce the level of the residual risks and hazards to complete elimination or an acceptable level based on approval. This must be confirmed by re-evaluation in the risk assessment.

Adopted organizational measures as well as the residual risks and hazards must be included in the relevant accompanying documentation (risk and hazard overview, operating and maintenance manuals, instructions etc.). Ensuring that all open items/task need to be closed or address by the completion of the SAT.

The design, delivery, and installation of the equipment (project) must enable any organizational measures to be fully implemented and trained before the equipment is put into regular operation. (It includes creation of working and organizational instructions, training of operators, workers, and maintenance personnel on the safe operation of the equipment, familiarization with the risks, safety and information and signs, etc.).

8. Whole-Body Entry to operating enclosures including Robotic Workplaces:

In dangerous working areas of machines or their parts, which are usually protected by guards, fencing and structures of machines or buildings and which can be accessed with the whole body, there can be significant hazards such as: hitting, trapping, or crushing by moving parts of machines. In addition, these can be put into operation automatically and move often unpredictably and unexpectedly. They can be started independently of the will of persons located in the danger area. In these areas, it may not be possible to escape to a safe place from the hazards and to escape from the area. The hazard can result in very serious or even fatal injuries. For this reason, it is necessary always technically secure the entry to these areas, eliminate the above risks and avoid the possibility of serious injury. This applies to machine operation, maintenance and servicing, repairs, cleaning, inspections and checks as well as any other activity of persons entering these areas.

1. Danger areas of machines must be adequately fenced, or the entry to these areas must be secured.

Devices as scanners, optical barriers, safety mats, etc. should be placed to make sure that a person safety

Page: 6/15



during/while in this area of the machine/station (e.g.: disconnecting and immediately stopping the machine, etc.)

- 2. If the danger area is fenced and provided with access doors, the following conditions must be met:
 - a. Doors may allow entry only when all dangerous moving parts and power are safely stopped, and the machine is in a safe position.
 - b. An adequate provision of emergency stop switches easily reached from all the places, where the presence and activities of persons who entered the machine (operation, maintenance, cleaning, inspection, housekeeping, etc.) can be assumed, must be placed in the danger area
 - c. From the place of operator machine operator there must be a clear view of the entire danger area to be able to make sure before starting the machine that there is no person in the danger area. If this is not provided, the equipment may not be started.
 - d. The equipment must be equipped with optical and acoustic warning system that gives a signal long enough before starting to allow any person located in the danger area to safely reach the emergency stop switch.
 - e. Where a clear view of the entire danger area is not provided from the place of operator machine operator (there is a place that is not visible), it should be otherwise technically ensured that the equipment cannot start if there is any person inside (e.g., using spatial scanners, optical barriers or trapped key system). The design of the safety system must also consider the need for detection of persons located on or under the equipment, or behind its parts or in any other blind spots in the danger area.
 - For other activities, maintenance, housekeeping, cleaning, repairs, adjustment, persons must use the LOTO system before entering the danger area, i.e., safe disconnection and locking of all power supplies (electrical, hydraulic, pneumatic, etc.) using a personal lock. Key to this lock must be held by the person concerned, if located in the danger area, always. The equipment must be equipped with LOTO with an approved captive, coded-key system.

9. Noise protection

The equipment must not emit noise which would lead to exceeding of the permissible exposure limits for noise in the workplace. For steady and variable noise, the equipment must not emit noise stronger than 77 dB (A) - unless there is lower limit specified in legislation or standards regarding the work performed at the workplace.

10.Maintenance

Equipment shall provide safe, easy, and protected access for routine maintenance

11. Emergency Stop

- a) Equipment shall provide safe environment and adequate amount of E-Stop switches easily reached from all the places, where the presence and activities of persons who entered the machine (operation, maintenance, cleaning, inspection, housekeeping, etc.) can be assumed, must be placed in the danger area.
- b) Emergency E-stop circuitry shall comply with the norms and standards from CE and UKCA.
- c) Emergency E-Stop Circuitry shall have dual line control type. The E-Stops will be integrated to the control system of the equipment (Machine, line, etc.) to have visibility and data collection capabilities.

Page: 7/15



12. Machine points

- a) All pinch points must be guarded and in-running nips as not to pose any hazard to operators or maintenance personnel.
- b) All Energy sources must have a safe control of hazardous energy release system when the Equipment is stopped for maintenance or service.
- c) Energy source that are meant for holding a part in the air, it required to have a control mechanism to ensure the part will not fall if the energy source is lost such as locking pin or other mechanical support.

13.Sites Requirements

Supplier must comply with all relevant HSE legal requirements and with local Aliaxis site HSE rules.

Aliaxis Authorization:

Supplier must obtain authorization from Aliaxis before:

- a) Engaging other 3rd parties
- b) Using or disconnecting any equipment belonging to Aliaxis (or other 3rd parties)
- c) Connecting equipment to site services (electricity, compressed air, water, drains, etc.)
- d) Disposing of any solid or liquid waste on site
- e) Bringing any work equipment or materials/chemical onto the site.

Permit-to-work

Supplier must obtain a permit-to-work each day before starting any job that involves:

- a) Work at height
- b) Hot work
- c) Critical lifting
- d) Confined space entry
- e) Ground disturbance
- f) Demolition
- g) Interventions on equipment requiring hazardous energy to be present

Personnel

Suppliers must:

- a) Assign a "Contractor Performing Authority" to supervise the work and ensure compliance to Site HSE rules, work method statements and permit-to-work requirements
- b) Provide workers who are competent, adequately trained, and with relevant certifications
- c) Ensure 3rd party workers remain within their assigned work areas and wear the required PPE
- d) Notify Aliaxis in advance of any changes in personnel

Page: 8/15



Risk management procedures

Suppliers must:

- a) Carry out a risk assessment for each job in advanced and use this to develop a work method statement
- b) Submit risk assessment and work method statements (SOPs) in advance for review by Aliaxis

Work Equipment & Ways of Working

Suppliers must:

- a) Maintain work equipment in good & safe working order with all certifications up to date
- b) Provide safe access equipment for work at height (Ex. Scaffolding, platforms)
 - a. Portable ladders must not be used, unless authorized by Aliaxis
 - b. Fixed scaffolds must be inspected after any changes (and at least once a week) by a competent person and tagged to indicate their status
- c) Ensure work equipment is stopped before any intervention, and any work involving disassembly (including guard removal) is done under lock-out/tag-out
- d) Ensure waste is disposed in-line with legal requirements and retain relevant disposal documentation

Incidents, near misses & unsafe conditions

Suppliers must stop work immediately & contact Aliaxis if:

- a) There is an HSE incident (Including injuries, environmental release, and near misses)
- b) Identify new risks
- c) Are unsure how to proceed safely

14.FAT Safety Checklist & Process

- a) Guarding and safety interlocks must be present and active for all phases during performance testing.
- b) In preparation for the acceptance test runs, it is expected that the supplier performed its *Pre-acceptance and Safety Checklists* review. It will be the responsibility of the supplier to address any issues that are not completed on the checklist.
- c) It is expected that during the tune-up phase the supplier has a plan to test the equipment prior to the actual preacceptance test runs. This is to acquire and demonstrate the confidence that the equipment is ready to pass the test runs on the first attempt. It is anticipated that appropriate statistically driven test runs are done ahead of time to gain such confidence and to minimize material usage and safety findings.

Page: 9/15





Checkl	Checklist		Answers		
			NO	N/A	
Catego	ry: General Safety Information				
1	Can you provide a full list of all essential health & safety requirements, transposed harmonised standards, national and European standards, and other technical specifications which your product has been designed against to compliant with?				
2	Has compliance to all above requirements been verified by a third party?				
3	Can you provide all require documentation for substances that the machine use or required for perform the task, maintenance, or cleaning (MSDS)?				
4	Is the product certified as compliant with European Law and affixed with CE mark?				
5	Can you provide a declaration of conformity to relevant laws and requirements?				
6	Are instructions and guidelines for transport, assembly, positioning, commissioning, running, maintenance, troubleshooting, decommissioning and disposal available in the first language of the buyer (buyer being the site not the person)				
7	Can you provide a list of safety risks associated with transport, assembly, positioning, commissioning, running, scheduled maintenance, unscheduled breakdowns, decommissioning and disposal of the product?				
8	Will adequate lifting fixtures be provided to allow item to be lifted safely?				
9	can you confirm that all moving or hazardous parts are adequately guarded by fixed or interlocked guards and provide a list of these guards along with a list of emergency stops. Are there any uncontrolled or inadequately controlled hazards relating to this equipment?				
10	Can you provide a list of restrictions that should be applied specific categories of person using or in the proximity of the product? (example people with pacemakers, expectant/nursing mothers)				
11	Have control panels been designed and positioned to minimise fatigue injuries and adjustable for comfort of the operator?				
12	Will access to areas that require routine maintenance be safe from exposure to hazards including all energy isolation/lock off points?				

Page: 10/15



Category: Working limits of product					
13	Can you provide information about levels of noise, fumes, dust, heat, cold, vibration, radiation generated by the equipment in normal and abnormal conditions? Please, provide information on a separate spreadsheet as an annex.				
14	Can you provide information on how the product has been designed to minimise levels of noise, fumes, dust, heat, cold, vibration, radiation?				
15	Can you provide a list of the safe working limits for the product and any by products from the equipment (example safe working load, hazardous fumes)				
16	Are any of the materials within the equipment hazardous under normal or abnormal conditions? Can you provide details?				
17	Can you provide information on the environment required for safe positioning and use of the product? Example, (humid, cold/hot environments)				
18	For lifting equipment will the safe working capacities be provided and clearly marked on the product?				
19	Are safe limits clearly shown on all gauges and are all gauges positioned so that they can be viewed clearly from a safe working area.				
20	Do you provide precautions for safe access especially heights and confined spaces?				
21	Can you provide recommended maintenance schedules for product, safety devices and associated ancillary parts?				
22	Will remote console be provided to allow for maintenance to be done away from the hazardous areas?				
	Chaddist	Answers			
Checklist		YES	NO	N/A	
Catego	Category: Safety devices				
23	Are emergency stop controls available and clearly marked at all points needed in all potential emergency situations (normal use, and maintenance)?				
24	Do emergency controls cut power and stop all motion dead immediately?				

Page: 11/15



25	Where motion continues after stop button has been pressed are timed guards in place to protect exposure until all motion has stopped?		
26	Will all hazards that cannot be made safe from accidental exposure have pictorial warning signs affixed at all points of exposure?		
27	Will all mechanical hazards be isolated by suitable and sufficient guarding? (exposed moving parts)		
28	Can you provide a list of all non-fixed guards that will be provided and the safety rating and standards of associated safety components?		
29	Will audible and visual alarms be fitted and clearly identified to denote abnormal situations? (Example pressures build up, safety control failure)?		
30	Will mobile lifting vehicles be fitted with audible and visible pedestrian warning devices for all directions of travel?		
31	Is there automatic shut off provided for hydraulic pumps in the event of a fire? Which can be linked to and activated by an external signal.		
32	Is internal pressure released when item is shut down?		
33	Has the equipment been designed to accommodate the collection of any by-product either recycled or not (sprues, chips, dust, fumes etc.)?		
34	Can you provide information on recommended pre inspection routines prior to use and then for ongoing use?		
35	If machine is run with 2 hand control, are the buttons sunken or provided with cowls to avoid cheating, tamper or bypass of the safety system?		
36	If E-stop can be used as main switch for controlling electricity into the equipment, has it been designed to be locked in an off position (LOTO)?		
Catego	ry: Electricity specific		
37	Can you provide information on risks from sources of energy in normal and abnormal conditions (example electricity, hydraulics, pneumatics, stored pressure)?		

Page: 12/15





38	Has equipment been designed to enable safe isolation and dissipation of all sources of energy?		
39	Has the product been designed to eliminate risk of electric shock during normal use and maintenance tasks when electrical panels and covers may be opened? If yes, please provide information on how?		
40	Will the product have sufficient devices for grounding the electricity?		
41	Will all switches and electric panels be labelled for identification and maintenance purposes?		
42	Will all exposed conductors be guarded?		
43	Will electrical equipment and/or Forklift vehicles classification meets area requirements (e.g. where explosive dust, flammable gases etc. are present)? *supplier needs to know our proposed location and environment for product to answer this		

Page: 13/15





15. Site commissioning safety checklist

		Answers			
	Checklist		NO	N/A	
	Category: General Safety Information				
1	Is the equipment affixed with CE mark?				
2	Does the site has a copy of the declaration and certificate of CE requirements compliance?				
3	Are instructions available for transport, assembly, positioning, commissioning, running, maintenance, troubleshooting, decommissioning and disposal available in the first language of the site?				
4	Have maintenance and statutory inspection requirements been recommended by the supplier?				
5	Are there any obvious dangerous elements of the equipment not previously identified by the supplier?				
6	Are all hazards clearly marked with signage that is easy to understand?				
7	Have all safety devices been provided as requested?				
	Category: Working limits of product				
8	Is noise generated from the equipment adequately controlled to avoid potential harm to people (users and those in the local area)? NOTE PERSONAL PROTECTIVE EQUIPMENT AND/OR TRAINING IS NOT AN ADEQUATE FIRST CONTROL				
9	Are airborne substances and by-products generated from the equipment adequately controlled to avoid potential harm to people? (example: waste, radiation, chemicals, oils, liquids, fumes, dusts) NOTE PERSONAL PROTECTIVE EQUIPMENT AND/OR TRAINING IS NOT AN ADEQUATE FIRST CONTROL				
10	Are airborne substances and by-products generated from the equipment adequately controlled to avoid potential harm to the surrounding building/equipment infrastructure? (example: will be chemical by products attack nearby steelwork such as overhead cranes?)				
11	Are hot and cold parts of the equipment adequately controlled to avoid potential harm to people (users and those in the local area)?				

Page: 14/15





12	Is any vibration generated by the equipment adequately controlled to avoid potential harm to people or nearby infrastructure/equipment? NOTE PERSONAL PROTECTIVE EQUIPMENT AND/OR TRAINING IS NOT AN ADEQUATE FIRST CONTROL		
13	Is it possible for any of the by-products of the equipment to exceed safe working control limits? (example concentration of fumes?) If so, have additional emergency procedures been written and trained out?		
14	Is the equipment sited in an adequate environment to avoid additional hazards? (example potential for damp air or poor ventilation)		
15	For lifting equipment, is the safe working load clearly shown?		
16	Are safe limits clearly shown on all gauges and are all gauges positioned so that they can be always viewed.		
17	Has safe access to routine maintenance and operator points been provided?		
18	Have all safety devices been tested to ensure they are working as required?		
19	Has a maintenance and routine inspection schedule been implemented/provided for all safety switches and devices aligned with manufacturers recommendations?		

Page: 15/15