How CE Marking Impacts Machinery Maintenance
TÜV SÜD UK Ltd in the UK

- 500+ Employees
- 22 UK Locations

- TÜV SÜD Product Service
- Nuclear Technologies
- TÜV NEL
- Wallace Whittle
- PMSS

Worldwide, there are over 20,000 staff at over 600 locations
Machinery Division Consultancy

- Preferred supplier on regulatory matters to the Processing and Packaging Machinery Association (PPMA)
- Seminars, workshops and university accredited five day training courses
- We will act as the Authorised Person in Europe to Hold Technical Files

We are **market leaders** in **machinery safety**, which covers machinery safety legislation and remedial engineering, providing solutions on a world-wide basis. Our experience in machinery safety compliance enables reassurance that your product has been independently assessed for compliance.
Machinery Safety Engineering Services

- **Engineering design**
  - Site survey and function design specification
  - Factory acceptance test
  - Installation and commissioning

- **Machine guarding**
  - Design, manufacture and installation of machine guarding and Safety Related Control Systems
  - Solutions include perimeter guarding, light curtains, scanners, interlocking etc.
It could be worse!
Life Cycle of a Machine

- Concept
- Specification
- Design
- Manufacture
- Installation
- Commissioning
- Run Machine as Design intent

PUWER

Danger Area

CE MARKING

Machine Disposal
- PUWER Reassessment
- Modifications & Refurbishment
- Periodic Testing & Inspection
- Training & Development
- PUWER Inspection
- Task Risk Assessment
Responsibilities

The Manufacturer

Simple guide to the Provision and Use of Work Equipment Regulations 1998

The User

Guide to application of the Machinery Directive 2006/42/EC
Before
After
SAFETY ROPE — WHEN OTHER SYSTEMS FAIL

FLIP-DOWN SUN GLASSES

ROLL BAR

HARD HAT WITH WIDE BRIM & EAR PROTECTORS

PADDED-BACK SEAT & HEAD RESTRAINT

BACK-UP LIGHTS
TAIL LIGHTS & DIRECTIONAL LIGHTS

SHOULDER HARNESS

AUTOMATIC, AIR-FILLED CHEST PROTECTOR

MAPS, IF YOU GET LOST & CHECK LIST BEFORE RIDING

BLUE-TAIL FLY REPELLENT

SEAT BELT

SELF STARTER (ACCESSORY)

KNEE PADS (JUST IN CASE) & QUILTED PANTS

SAFETY NET ALL AROUND

4 WHEELS TO KEEP HORSE UPRIGHT IN CASE HE SLIPS — HENCE NOT ENDANGERING THE RIDER.

DUAL CINCH

NON-SKID SPARK SUPPRESSORS

E.P.A. EMISSIONS CONTROL SYSTEM

GRAB-RAIL

SAFETY SWITCHES & "HOT LINE" TO INSURANCE COMPANY

STEEL-TOED STIRRUPS

PRESCRIPTION SAFETY GOOGLES TO INSURE HORSES GOOD VISION.
Directives that could apply

- The Machinery Directive 2006/42/EC.
- The Low Voltage Directive 2006/95/EC.
- The EMC Directive 2004/108/EC.
- The Pressure Equipment Directive 97/23/EC.
- The Explosive Atmospheres, ‘ATEX’ Directive 94/9/EC
Why do we have to comply

Because all of the European directives are brought into UK law by the issue of Regulations that make it a criminal offence punishable by fines and imprisonment not to comply.
The Machinery Directive – How to comply

- Demonstrate compliance with the Essential Health and Safety Requirements.
- Carry out the appropriate conformity assessment procedure (Technical File).
- Draw up and issue the Declaration of Conformity or Incorporation.
- Apply the CE Mark.
- Make sure that it is safe.
This Directive applies to the following products:

• (a) machinery;
• (b) interchangeable equipment;
• (c) safety components;
• (d) lifting accessories;
• (e) chains, ropes and webbing;
• (f) removable mechanical transmission devices;
• (g) partly completed machinery;
Firstly what is a machine?

- An assembly fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application.
Is an electric motor a machine?
Significance of CE
Definitions of machinery

- An assembly of machines and / or partly completed machinery which, in order to achieve the same end are arranged and controlled to function as an integral whole.

- For example, a Complex Assembly.
Definitions

Lifting

• An assembly of linked parts or components at least one of which moves and which are joined together, intended for lifting loads and whose only power source is direct applied human effort are included in the directive.

• Lifting accessory means a component or equipment not attached to the lifting machinery, allowing the load to be held, which is placed between the machinery and the load or on the load itself.
Definitions - lifting

- Or which is intended to constitute an integral part of the load and which is independently placed on the market; slings and their components are also regarded as lifting accessories;
Definition of a safety component

- Which serves to fulfil a safety function,

- which is independently placed on the market,

- the failure and/or malfunction of which endangers the safety of persons.
Safety devices – Annex V

• Extraction systems.
• Guards and protection devices.
• Control devices for calling lifting appliances and anti fall devices for hoists.
• Protective devices designed to detect the presence of a person.
• Safety belts and seat harnesses.
• Hydraulic non return valves where they are used to prevent falls.
Safety devices – Annex V cont

- Electro sensitive devices.
- Monitoring devices for loading and movement control in lifting machinery.
- Safety logic units for E stops or interlocks.
- Solenoid valves controlling dangerous movements of machinery.
If you are creating a complex assembly by interlinking a series of existing machines you are in effect creating something new. Therefore who ever is carrying out the work must ensure that the whole assembly complies with the Directive. Regardless of the age of the machines.
If you are altering the function or performance of a machine or complex assembly you are again creating something new and must ensure that the Directive is complied with.
Changing a machine / component

Changing a machine in a complex assembly or component in a single machine.

If the function or performance are not altered this is classed as a repair and no action other than a risk assessment and compliance with PUWER 98 is required.
In-house machinery

- where the manufacturer of relevant machinery himself puts that machinery into service.
- having imported machinery from a country or territory outside the EEA, puts that machinery into service.

- First use in Europe requires CE marking to be in place when the machine or assembly is put into service.
Risk Assessment

• Carried out across all phases of the lifecycle of the machine
  – Design
  – Prototype
  – Installation
  – Operations
  – Process
  – Maintenance
Risks must be controlled in the following order:

1. **Initial Design**
2. **Design Out Hazards**
3. **Protective Measures**
4. **Safety Controls**
5. **Information**
6. **Organisation**
7. **Training**
8. **Safe Systems of Work**
If you don’t comply......

- Non compliance could result in prosecution and penalties.
- On summary conviction a fine not to exceed the statutory maximum (£20,000) and or twelve months in prison.
- On conviction on indictment an unlimited fine and or two years in prison.
Penalties

- Failure to provide a Technical File.
- Failure to provide operating instructions.
- Failure to provide a Declaration of Conformity.
- Incorrect application of the CE Mark.
- None application of the CE Mark.
- A fine not exceeding level 5.
- (£20,000.00 at this time).
Four steps to compliance

- Complying with the EHSR’s
- Compiling the Technical Construction File (TCF)
- Raising the Declaration of Conformity
- Affixing the CE Mark
EN Standards

• The EHSR’s are mandatory, the EN Standards are not however:

• “Machinery manufactured in conformity with specified published European Harmonised standards will be presumed to comply with Essential Health and Safety Requirements covered by those standards”
There are Three Types of Standard

• “A” type apply to all machines.

• “B” type are designed to promote safety and split in to B1 and B2.

• “C” type apply to a specific type of machine.
EN Standards

A

BS EN ISO 12100:2010
Safety of machinery
Basic concepts, general principles for design.
Risk Assessment and risk reduction

B

BS EN 60204 - 1
Electrical Equipment

BS EN 13849-1
Safety-related parts of control systems.

BS EN ISO 13850
Emergency Stop

C

TYPE C STANDARDS for Machines

SPECIFIC PROTECTIVE DEVICE STANDARDS
2 Hand Controls
Light Curtains
Safety Switches etc
Examples of “B” Type Standards

- BS EN 953 Relates to the selection and manufacturing of Guards.
- BS EN 349 Relates to minimum gaps to prevent Crushing of the whole body.
- BS EN ISO 13857 Relates to the positioning of guards to protect the upper limbs and the lower limbs.
Examples of C Type Standards

- BS EN 415 Series “Safety of Packaging Machines” in 9 parts. Part 4 applies to Palletisers and De-Palletisers.

- BS EN 10218 “Industrial Robots Recommendations for Safety”.

- BS EN 12417 “Safety of Machine tools Machining Centres”.

EN Standards
• New Standard to replace EN1088
Two Main Reasons

1. EN 1088 is now outdated due to new technologies and new ideas.
2. The Health and Safety Executive has recently published a report entitled *Identifying the human factors associated with the defeating of interlocks on Computer Numerical Control (CNC) machines* (reference RR974).
ISO 14119 Types of Interlocking

Type 2 interlocking device — Example

Key:
1. position switch
2. actuator (shaped tongue)

Figure B.1 — Position switch with coded tongue actuator
How to comply step 2 the Technical Construction File (TCF)

• The TCF will be required to be produced by the responsible person if there is a reason to doubt that the machine does not conform with the Directive.

• It can be kept electronically however you must be able to assemble it in a time given by the enforcement authorities.
How to comply step 2 the Technical Construction File (TCF)

- The file must be kept for a period of ten years after production of the last machine of the type that the TCF refers to.

- The TCF is the only way to demonstrate that you have complied with the EHSR’s and other provisions of the Directive.
Declarations

Step 3

Declaration of Conformity or Incorporation.

This has to accompany the machine.
Changes to the Declaration of Conformity

• Name and address of the person who is authorised to compile the Technical File, who must be established in the European Community.

• Where appropriate a statement confirming declaration of conformity with other applicable directives.

• Must be typewritten or handwritten in capital letters.
The Declaration of Incorporation is used with a machine which is specifically designed to be incorporated into a complex assembly and not capable of independent work.
The CE Mark denotes that the manufacturer has declared his product in compliance with all applicable Directives.

Affixing the CE Mark

Step 4:

It is illegal to affix the CE mark to a machine unless it complies with all applicable Directives.

The CE Mark denotes that the manufacturer has declared his product in compliance with all applicable Directives.

The CE marking must be affixed in the immediate vicinity of the name of the manufacturer or his authorised representative and be applied using the same technique.
Implementing the Work Equipment Directive
89/655/EEC.

Provision and Use of Work Equipment Regulations 1998

APPLIES TO ALL WORK EQUIPMENT NOW REGARDLESS OF AGE INCLUDING CE MARKED EQUIPMENT.
Regulation 10: Community Requirements

• Requires that an Employer must ensure that any equipment that is subject to European Directives complies with all applicable Essential Health and Safety Requirements of the Directives that apply to it.

• Declaration of Conformity / Incorporation.

• Relevant paperwork, documents, instructions.
Regulation 18: Control Systems

Q. Is the control system fail safe?
   Electrical
   Pneumatic
   Hydraulic

Q. Will a fault lead to a dangerous situation.
Safety Related Control Systems
ISO 13849

IEC 62061

Both these standards look at the Architecture of the safety system.
Functional Safety
Out of control
Why control systems go wrong and how to prevent failure?

(Out of control, 2nd edition 2003, Health & Safety Executive HSE – UK)
IEC 62061

An electrical standard to be used when the safety of the machinery is being controlled by a specifically designed safety PLC.

Can only be used on electrical installations.
ISO 13849-1

Is a replacement for EN 954-1 can be used for any energy source.

But if a specifically designed PLC is controlling the safety system please refer to IEC 62061.
ISO 13849-1

- Introduces Performance levels (probability of a dangerous failure per hour) a,b,c,d,e.
- Based on the Safety Related Parts of the control system (SRP/CS).
- Data to be obtained from manufacturer Mean Time To (dangerous) Failure MTTD.
Four stage approach:

- Perform a risk assessment
- For the identified risks, allocate the safety measure (Performance Level (PL))
- Devise a system architecture that is suitable for the Performance Level
- Validate the design to check that it meets the requirements of the initial risk assessment
Functional Safety

EN 13849-1
(Risikograph)

Performance level

Low risk

PLr

High risk

S = Severity of injury
S1 = Slight (normally reversible) injury, S2 = Serious (normally irreversible) injury or death
F = Frequency and/or exposure to the hazard
F1 = Seldom to quite often and/or the exposure time is short, F2 = Frequent to continuous and/or the exposure time is short
P = Possibility of avoiding hazard or limiting harm
P1 = Possible under special conditions, P2 = Scarcely possible