

## **Safety Auditing**

### **The Audit Trail for Safeguarding Devices**

### **The Conformity Assessment Process and Evidence of Compliance**

# U.S.A. Machine Safety Standard For Safeguarding Devices



- New!
- ANSI
- The US has recently adopted the international standard IEC-61496 parts 1&2 as an American National Standard; ANSI 61496-1&2.  
Part 1: Electro Sensitive Protection Equipment  
Part 2: Active Optoelectronic Protection Devices
- Light Curtains
- This standard pertains to sensing type safety devices; light curtains, capacitive loops, RF devices, single safety beams, opto touch switch, etc.
- Safety Integrity Level
- This standard puts forth very arduous safety requirements that these products must meet. Few safeguarding devices, currently on the market, achieve the required high level of safety integrity
- OSHA
- As an American National Standard, it becomes law under OSHA's Code of Federal Regulation.  
*1910.212 General requirements for all machines*  
*(ii) The point of operation of machines, whose operation exposes an employee to injury, shall be guarded. The guarding device shall be in conformity with any appropriate standards.*
- Conformity Assessment
- To demonstrate "conformity" to government regulations, the product's design must be evaluated against the product standard and must prove compliance. (See ANSI/ISO Conformity Assessment)
- 3<sup>rd</sup> Party Certified
- To ensure 'compliance' the product evaluation must be conducted by independent 3<sup>rd</sup> party deemed competent to perform the evaluation and authorized by a government body.
- Certificate
- Upon the product being deemed compliant it is issued a certificate to IEC-61496 parts 1&2 by the certifying body. And for notification to government authorities, the label affixed to the product must state;
    - The certifying body
    - The certification number
    - The standard – IEC-61496-1&2
- QS-9000 3<sup>rd</sup> Edition  
ISO-9000 (2000)
- Upon the product coming under governmental safety constraints, it then is subject to government audits plus it falls into the quality system audit process, whereby one is required to "provide documentation showing compliance", i.e. "evidence of compliance" (see QS-9000 clauses containing Safety Requirements)
- Compliance
- Evidence of compliance is the certificate to IEC-61496 parts 1&2 (ANSI 61496 parts 1&2) and the product's label stating certification to IEC-61496-1&2.
- Non-compliance
- If one cannot produce the 'evidence of compliance' (i.e. certificate and label stating IEC-61496-1&2) then the auditor cannot deem the product compliant and must issue a "non-compliance".

# Canadian Machine Safety Standard For Safeguarding Devices

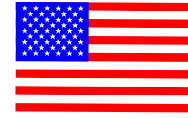


New!

- IEC/ISO
- The Ontario Ministry of Labor has recently adopted several international machine safety standards in their "*Guideline for Industrial Establishments regarding Pre-Start Health and Safety Reviews.*" One of these standards is IEC-61496 parts 1&2.  
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- MOL
- As of October 7, 2000; under Ontario Regulation 528/00 **these requirements became law**
- Conformity Assessment
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- **Evidence of compliance** is the certificate to IEC-61496 parts 1&2 (ANSI 61496 parts 1&2) and the product's label stating certification to IEC-61496-1&2.
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## Additional Requirements



### Warnings

The product must be installed in accordance with the Manufacturer's Instructions. All 'warnings' must be adhered.

Example of common misapplications:

1. Light curtain instructions generally warn against the sensing zone being close to surface(s) that can reflect its light beam(s). Some manufacturers specify a minimum closeness of 4.1" (100 mm) which expands with longer spanning distances up to 40".
2. Laser scanner instructions warn against usage where angular refraction can occur.
3. Many sensing device instructions warn against usage where environmental disturbances occur, i.e. RF, EMI, temp, etc.

**Note:** Standard IEC-62046 provides guidance of the '*Application of Presence Sensing Protective Equipment.*'

### Point of Operation

Safeguarding devices used at the Point of Operation must also;

- At power-on, validate the entire safety system prior to allowing normal operation, i.e. self diagnostic and test of safety system.
- Where machine motion is needed to test the safety system (i.e. mute inputs, stopping devices) the test must be performed under enhanced safety measures such as two hand control.
- All devices in the stopping chain must be monitored, i.e. hydraulic/pneumatic valves.
- When any stopping device's reaction time exceeds the time allotted for in the safety distance formula the system must go to lockout.
- Upon actuation of the safety device during hazardous motion the system must go to a restart interlock condition.

For more details (see Why Front End Sensors Don't Work for Point of Operation Safeguarding)

### Documentation

The machine must undergo a formal process for 'Risk Assessment and Hazard Abatement.' This must be documented and kept with the machine. Safety devices used for Hazard Abatement must be traceable to a national or international standard.

### IEC-61508 Part 1 - 7

The entire safety control system must comply to IEC-61508 '*Functional Safety of the Safety Related Control System.*' This requires:

- All software used in the safety control system be 'safety software.'
- Separation of the safety control function from the machine control function.
- The system maintain a 'Safety Integrity Level' of a probability of dangerous failure of  $10^{-4}$  year.
- The system 'safety integrity level' defaults to the weakest link.

### Grandfathering

#### Chart 1 – Decision Tree for existing equipment

<b>1</b>	Was a Pre-Start Health and Safety Review carried out when the apparatus, structure, protective element, or process was originally installed or was an exemption documented?	Yes	Go to 3
		No	Go to 2
<b>2</b>	Is the apparatus, structure, protective element, or process currently in compliance with the <i>Regulations for Industrial Establishments</i>	Yes	Go to 3
		No	<b>Pre-Start Health and Safety Review required</b>
<b>3</b>	Are the modifications to the apparatus, structure, protective element, or process such that new or modified engineering controls or other measures would be required to comply with the applicable provisions of the <i>Regulations for Industrial Establishments</i> ?	Yes	<b>Pre-Start Health and Safety Review required</b>
		No	<b>Pre-Start Health and Safety Review not required</b>