

A Compendium of:  
ISO-9000 (2000)  
Quality Management System

New Safety Requirements  
affects the:

- Production Process
- Purchasing Requirements
- Machinery Used
- Machinery Purchased
- Audit

• Who:	Applies to all manufacturers claiming compliance to ISO-9000 and their machine suppliers
• What:	ISO-9001 (2000) added 'safety' to the requirements
• Where:	Global
• When:	Now!
• How:	See excerpts on New Safety Requirements and Auditing to those requirements

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## Introduction

### **New ISO-9000**

The following is a compendium of salient requirements found in the new ISO-9000 (2000 edition) as they apply to machine safeguarding. These requirements are applicable to the production process of manufacturers and to equipment suppliers.

Included within the new ISO-9000 Quality Standard is the requirement to be aware of new government regulations and to comply with government regulations. For machine safety, the government regulations have changed within Canada and the USA (see below). The change has occurred through workplace safety authorities endorsing the international machine safety standards; by direct reference or by adoption through national standards. Outside auditors and internal auditors are obligated to audit for compliance to regulations.

In many cases equipment will be required to be upgraded to meet the 'New' higher safety requirements being set forth in the new international standards below.

### **New Machine Safety Standards**

- IEC - 61496 - 1 & 2 (ANSI/UL 61496 - 1 & 2) Safety of Machinery Electro Sensitive Protective Equipment.
- IEC - 62046 (draft '00) Safety of Machinery - Application of Presence Sensing Protective Equipment (PSPE) to Machinery.
- IEC - 61508 ('00) Functional Safety - Safety Related Control Systems.
- ISO - 12100 - 1 & 2 ('00) Safety of Machinery - Basic Concepts, general principles for design.

For more information on above standards, go to [www.frostcontrols.com](http://www.frostcontrols.com)  
To order ISO-9000 (2000) go to American Society for Quality (ASQ), website @ [www.asq.org](http://www.asq.org).

### **New Regulations**

As of October '00, Canadian Regulation 528/00 mandates compliance to above international standards.

As of February '01, OSHA's ruling on USA Regulation 1910.212 mandates compliance to IEC-61496 parts 1 & 2(adopted as ANSI-61496 parts 1 & 2)

Excerpts	Comments
<p><b>3. Key terms and definitions for machine safety</b></p> <p><b>3.12 requirement</b> need or expectation that is stated, generally <b>implied or obligatory</b></p> <p>NOTE 1 "Generally implied" means that it is custom or common practice for the <b>organization</b> (3.3.1), its <b>customers</b> (3.3.5) and other <b>interested parties</b> (3.3.7), that the need or expectation under consideration is implied</p> <p>NOTE 2 A qualifier can be used to denote a specific type of requirement, e.g. product requirement, quality management requirement, customer requirement.</p> <p>NOTE 3 A specified requirement is one which is stated, for example, in a <b>document</b> (3.7.2).</p> <p>NOTE 4 <b>Requirements can be generated by different interested parties.</b></p> <p><b>3.3.7 interested party</b> person or group having an interest in the performance or success of an <b>organization</b> (3.3.1)</p> <p>EXAMPLE Customers (3.3.5), owners, people in an organization, suppliers (3.3.6), bankers, unions, partners or <b>society</b>.</p>	<p>Workplace authorities (regulators) are 'interested parties' and they have put forth the obligatory requirement (regulation) that safeguarding equipment shall conform to their appropriate product standards, (see introduction).</p> <p>Workplace authorities are the voice of society at large, who are stakeholders in workplace safety because they are the ones that bear the brunt of the cost of injuries via social programs.</p>
<p><b>3.2.13 continual improvement</b> recurring activity to increase the <b>ability to fulfill requirements</b> (3.1.2)</p> <p>NOTE The <b>process</b> (3.4.1) of establishing objectives and finding opportunities for improvement is a continual process through the use of <b>audit findings</b> (3.9.6) and <b>audit conclusions</b> (3.9.7), analysis of data, management <b>reviews</b> (3.8.7) or other means and generally leads to <b>corrective action</b> (3.6.5) or <b>preventive action</b> (3.6.4)</p> <p><b>3.6.1 conformity</b> fulfillment of a <b>requirement</b> (3.1.2)</p> <p><b>3.6.2 nonconformity</b> <b>non-fulfillment of a requirement</b> (3.1.2)</p>	<p>Where audit findings discover non-compliant safeguarding products and/or methods, it requires corrective action under the continual improvement clause.</p>
<p><b>3.8.4 verification</b> confirmation, through the provision of <b>objective evidence</b> (3.8.1), that specified <b>requirements</b> (3.1.2) have been fulfilled</p> <p><b>3.8.5 validation</b> confirmation, through the provision of <b>objective evidence</b> (3.8.1), that the <b>requirements</b> (3.1.2) for a specific intended use or application have been fulfilled</p> <p><b>3.9.5 audit evidence records</b> (3.7.6), statements of fact or other <b>information</b> (3.7.1) relevant to the agreed <b>criteria</b> (3.9.4) and which can be <b>cross-checked</b></p>	<p>For audit evidence, records must be provided, that verify and validate, that there is 'objective evidence' that the safeguarding equipment conforms to its appropriate product standard, i.e. 'requirement'. Such evidence is independent 3<sup>rd</sup> party certification, by an authorized body, that the safeguarding equipment meets the requirements set forth in its product standard, i.e. the cross-check.</p>

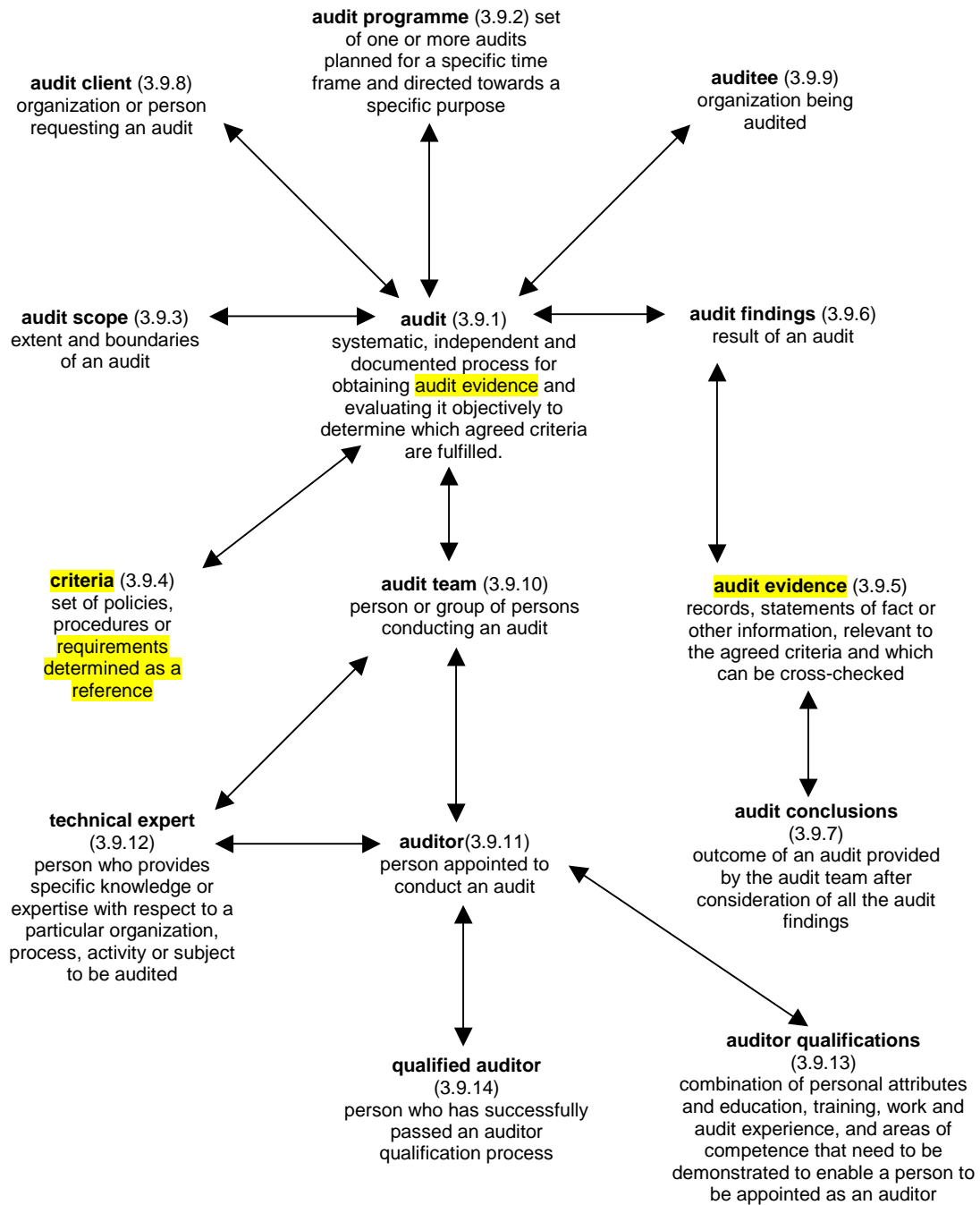


Figure A.12 - Concepts relating to audit (3.9)

Excerpts	Comments
<p><b>1 Scope</b></p> <p><b>1.1 General</b></p> <p>This International Standard specifies requirements for a quality management system where an organization</p> <ul style="list-style-type: none"> <li>a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and</li> <li>b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.</li> </ul> <p>NOTE In this International Standard, the term "product" applies only to the product intended for, or required by, a customer.</p>	<p>Machinery supplied must meet the "new" regulatory requirements set forth by governments (see introduction)</p>
<p><b>1.2 Application</b></p> <p>Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that fulfills customer and applicable regulatory requirements.</p>	<p>The organization is not permitted to exclude the requirement set forth in regulations.</p>
<p><b>5.1 Management commitment</b></p> <p>Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by</p> <ul style="list-style-type: none"> <li>a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements.</li> </ul>	<p>Top management must provide resources in order to comply with regulatory requirements.</p>

Excerpts	Comments
<p><b>4.2 Documentation Requirements</b></p> <p><b>4.2.3 Control of documents</b></p> <p>Documents required by the quality management system shall be controlled. Quality records are a special type of document and shall be controlled according to the requirements given in 4.2.4.</p> <p>A documented procedure shall be established to define the controls needed</p> <p>a) to approve documents for adequacy prior to issue,  b) to review and update as necessary and re-approve documents,  c) to ensure that changes and the current revision status of documents are identified,  d) to ensure that relevant versions of applicable documents are available at points of use,  e) to ensure that documents remain legible and readily identifiable,  f) to ensure that documents of external origin are identified and their distribution controlled, and  g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.</p>	<p>External documents such as safety standards, regulations, risk assessments, instructions for use, etc; must be controlled; i.e. identified, kept current, approved for use.</p>
<p><b>4.2.4 Control of quality records</b></p> <p>Quality records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Quality records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of quality records.</p>	<p>Documents that provide 'evidence of conformity to requirements', in particular to regulatory requirements, must be obtained and readily retrievable upon request by auditors, i.e. quality auditor, government inspectors, etc. 'Evidence of conformity' for machine safeguarding equipment is the 'certificate of conformity.'</p> <p>To - the current standard  By - authorized 3<sup>rd</sup> party</p> <p><b>Note:</b> Safeguarding equipment claiming conformity to IEC-61496-1&amp;2 (light curtain standard) must also state on its product label:</p> <ul style="list-style-type: none"> <li>• the standard - IEC-61496-1&amp;2</li> <li>• the certification number</li> <li>• the certification body</li> </ul>

Excerpts	Comments
<p><b>7.2 Customer related processes</b></p> <p><b>7.2.1 Determination of requirements related to the product</b></p> <p>The organization shall determine:</p> <ul style="list-style-type: none"> <li>requirements not stated by the customer but necessary for specified use or known and intended use,</li> <li>statutory and regulatory requirements related to the product.</li> </ul> <p><b>7.2.2 Review of requirements related to the product</b></p> <p>Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.</p> <p><b>3.6.3 defect</b> non-fulfillment of a requirement (3.1.2) related to an intended or specified use.</p>	<p>The machine sector is obligated to keep abreast of the new and/or changes in regulations that affect their products, plus must amend their product requirements; even if the customer is unaware of the change(s) and has not specified the change(s).</p> <p><b>Note:</b> Where safeguarding equipment is used, which does not comply with the current standards that are referenced by regulations the supplier may be deemed as supplying a 'defective' product and may be required to retrofit the safeguarding equipment at their own expense. (see Annex A)</p>
<p><b>7.3 Design and development</b></p> <p><b>7.3.2 Design and development inputs</b></p> <ul style="list-style-type: none"> <li>applicable statutory and regulatory requirements.</li> </ul> <p><b>7.3.3 Design and development outputs</b></p> <ul style="list-style-type: none"> <li>specify the characteristics of the product that are essential for its safe and proper use.</li> </ul> <p><b>7.3.5 Design and development verification</b></p> <p>Verification shall be performed to ensure that the design and development outputs have satisfied the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).</p> <p><b>7.3.6 Design and development validation</b></p> <p>Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of fulfilling the requirements for the specified or known use or application. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).</p>	<p>As part of the machine design process the supplier must evaluate the regulatory requirements and must implement those required for safe use. These requirements must be specified, verified, validated and recorded. This document (i.e. the risk assessment and hazard abatement) is a "quality record" (see 4.2.4) and must provide "evidence of conformity" i.e. safeguarding equipment certificate.</p>

Excerpts	Comments
<p><b>7.4 Purchasing</b></p> <p><b>7.4.1 Purchasing process</b></p> <p>The organization shall ensure that purchased product conforms to specified purchase requirements.</p> <p>The organization shall evaluate and select suppliers based on their ability to supply product in accordance with organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).</p> <p><b>7.4.2 Purchasing Information</b></p> <p>Purchasing information shall describe the product to be purchased, including where appropriate</p> <ul style="list-style-type: none"> <li>requirements for approval of product, procedures, processes and equipment.</li> </ul> <p><b>7.4.3 Verification of purchased product</b></p> <p>The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.</p>	<p>The purchased products must conform to specified requirements (i.e. applicable regulatory requirements) and the product(s) must "provide evidence of conformity" (i.e. certificate). The organization must evaluate suppliers based on their ability to supply products that conform. The organization must implement methods for ensuring that purchased product are inspected for compliance.</p>
<p><b>7.5 Production and service provision</b></p> <p><b>7.5.1 Control of production and service provision</b></p> <p>The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable</p> <ul style="list-style-type: none"> <li>the use of suitable equipment.</li> </ul> <p><b>7.5.2 Validation of processes for production and service provision</b></p> <p>Validation shall demonstrate the ability of these processes to achieve planned results.</p> <p>The organization shall establish arrangements for these processes including, as applicable;</p> <ul style="list-style-type: none"> <li>defined criteria for review and approval of the processes,</li> <li>approval of equipment and qualification of personnel.</li> </ul>	<p>The production process and equipment must also conform to the applicable regulatory requirements, and must demonstrate compliance.</p>

## Excerpts

## Comments

### 8.2.2 Internal audit

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.

The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

### 8.2.3 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

### 8.2.4 Monitoring and measurement of product

Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4).

### 8.3 Control of nonconforming product

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

### 8.5.2 Corrective action

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence.

Internal audits must audit for compliance to regulatory requirements. Machines must be equipped with compliant safeguarding equipment and the 'quality record' must "provide evidence of conformity" i.e. certification to appropriate standard.

Where nonconformities are discovered they must be corrected without undue delay. The nonconforming product must be removed from use and must be prevented from unintended use.

## Annex A

### CONFORMITY

## Product Safety Non-Compliance May Increase Manufacturers' Liability

Manufacturers who fail to ensure that their products meet all relevant product safety requirements could wind up on the short end of a defective product liability lawsuit, according to an American corporate counselor.

William Ruane of the American Home Product Corporation contends that the recent "restatement" of U.S. product liability law could allow plaintiffs in liability cases to claim that **a product is defective if it violates relevant product safety statutes or regulations.**

Ruane was one of several speakers during recent two-day conference in Brussels on strategies for defending against product liability litigation in the United States and the European Union (EU). The conference, sponsored by the United States Defense Research Institute, covered many aspects of the U.S. legal system and was intended to provide EU officials and manufacturers with a greater understanding of the ins and the outs of U.S. product liability law.

While compliance with relevant safety requirements is not conclusive proof that a product is not defective, according to Ruane, failure to comply can lead to the conclusion that the product is defective "per se", which may serve as the basis for the award of significant monetary damages in product liability cases.

106th CONGRESS

2d Session

**S.3014**

To amend title 18 of the United States Code to penalize the knowing and reckless introduction of a defective product into interstate commerce.

## **IN THE SENATE OF THE UNITED STATES**

**September 7, 2000**

Mr. SPECTER introduced the following bill; which was read twice and referred to the Committee on the Judiciary.

### **A BILL**

To amend title 18 of the United States Code to penalize the knowing and reckless introduction of a defective product into interstate commerce.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled.*

### **SECTION 1. DEFINITIONS.**

(a) A 'defective' product is one with a flaw in design, manufacture, assembly, or instruction which renders the product dangerous to human life and limb beyond the reasonable and accepted risk associated with such or similar products lacking such a flaw.

(b) To 'introduce' a product into the stream of interstate commerce is to manufacture, assemble, import, sell, or otherwise produce or transfer the product in question.

(c) 'Person' means the employees of any corporation, company, association, firm, partnership, or other business entity.

(d) 'Serious bodily injury' means bodily injury which involves--

(1) a substantial risk of death;

(2) extreme physical pain; or

(3) protected or impairment of the function of a bodily member, organ, or mental faculty.

### **SEC. 2. ENACTMENTS.**

(a) A person who in gross deviation from a reasonable standard of care introduces into interstate commerce a product known by that person to be defective which causes the death of any individual shall be guilty of murder in the second degree and shall be imprisoned for a term of up to fifteen years.

(b) A person who in gross deviation from a reasonable standard of care introduces into interstate commerce a defective product which causes serious bodily injury to any individual shall be imprisoned for a term of up to 5 years.

**A Compendium of:**

**ISO/TS 16949**  
**International Standards Organization**

**for**

**Automotive Suppliers**

**[QS-9000 International Version]**

**New Safety Requirements for Production, Process and Equipment**

- |                 |  |
|-----------------|--|
| • <b>Who:</b>   | <b>Applies to all suppliers to all the Automotive Companies</b>                              |
| • <b>What:</b>  | <b>ISO-9001 with Automotive specific requirements :<br/>International version of QS-9000</b> |
| • <b>Where:</b> | <b>Global</b>  |
| • <b>When:</b>  | <b>Now</b>   |
| • <b>How:</b>   | <b>See excerpts on New Safety Requirements and Auditing to those requirements</b>            |

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6. "New" Machine Safety Standards
7. Light curtain marketplace confusion

Who: Applies to all suppliers to all the Automotive Companies

What: ISO-9001 with Automotive specific requirements  
: International version of QS-9000

Where: Global

When: Now

How: See excerpts on New Safety Requirements and Auditing to those requirements

## 1.

### Introduction

The following is a compendium of salient safety requirements as it applies to safeguarding machinery used and/or purchased by the automotive suppliers. These requirements are applicable to the production process of part suppliers and to the product compliance of equipment suppliers.

In many cases equipment will be required to be upgraded to meet the “New” higher safety requirements being set forth in the new international standards below.

- IEC – 61496 – 1 & 2 (ANSI/UL 61496 – 1 & 2) Safety of Machinery Electro Sensitive Protective Equipment.
- IEC – 62046 (draft '00) Safety of Machinery – Application of Personnel Sensing Protective Equipment (PSPE) to Machinery.
- IEC – 61508 ('00) Functional Safety – Safety Related Control Systems.
- ISO – 12100 – 1 & 2 ('00) Safety of Machinery – Basic Concepts, general principles for design.

For more information on above standards, go to [www.frostcontrols.com](http://www.frostcontrols.com)

To order ISO/TS 16949 go to International Automotive Oversight Bureau (IAOB)  
Website @ [www.iaob](http://www.iaob)

2. **“Special Characteristics” pertains to safety**  
**ISO/TS-16949 Excerpts:**

## **“Special Characteristic”**

Annex A  
(normative)

### **Terms and definitions**

#### **A.55** **special characteristics**

- product or process characteristic subject to variation which may affect safety or compliance with regulations

Annex B  
(normative)

### **Control Plan**

#### **B.1 Phases of the control plan**

The control plan shall cover three distinct phases as appropriate.

- c) Production: documentation of product/process characteristics

#### **B.2 Elements of the control plan**

The supplier shall develop a control plan that includes, at a minimum, the following contents.

- b) **Product control**
  - product-related special characteristics
- c) **Process control**
  - process-related special characteristics

Annex C  
(informative)

### **Special characteristics**

Where no customer-specific symbols and definitions for special characteristics are defined, the following chart is provided as a suggested guideline



Product characteristic or process parameter which affects a product's **safety or compliance with regulatory requirements**.

## 4.

## The Law States

OSHA:

29 CFR

**§ 1910.212 General requirements for all machines.**

(a) Machine guarding – (1) Types of guarding

**(3) Point of operation guarding (i)**

Point of operation is the area on a Machine where work is actually performed upon the material being processed.

(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.

## EU Machine Safety Directive

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### 1.2 Controls

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#### 1.2.1 Safety and reliability of control systems

Control systems must be designed and constructed so that they are safe and reliable, in a way that will prevent a dangerous situation arising. Above all they must be designed and constructed in such a way that:

- they can withstand the rigors of normal use and external factors,
- errors in logic do not lead to dangerous situations.

## 5.

## USA Compliance to Safety Standards

Received 6/98

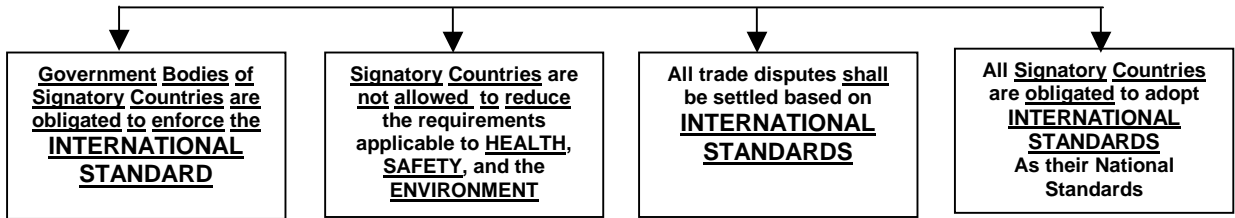
<b>Products or Services</b>	<b>EQUIPMENT AND MATERIALS USED IN THE WORPLACE</b>
<b>Department/Agency</b>	U.S. Department of Labor (DOL) Occupational Safety and Health Administration (OSHA) Directorate of Technical Support NRTL Program, Room 3653 200 Constitution Ave., NW Washington, DC 20210 Phone: (202) 219-7056 FAX: (202) 219-7068 e-mail: jennifer.silk@osha-no.osha.gov or bernard.pasquet@osha-no.osha.gov URL address: <a href="http://www.osha-slc.gov/SLTC/NRTL/index.html">http://www.osha-slc.gov/SLTC/NRTL/index.html</a>
<b>Initiated</b>	<i>Federal Register</i> Notices dated April 12, 1988 pages 12102-12125 and supplemental requirements in notice dated March 9, 1995, pages 12980-12985
<b>Compliance</b>	<b>Mandatory</b>
<b>Authority</b>	Occupational Safety and Health Act of 1970, P.L. 91-596. 29 CFR Part 1910 – Occupational Safety and Health Standards for General Industry, Section 1910.7.
<b>Aim</b>	To provide protection to the nation's workers on their job by reducing or eliminating the various hazards to which workers may be exposed. <b>Certain equipment because of its nature or the types of hazards that may develop while in use is required to be listed, labelled, or approved by third party laboratories</b> accredited by OSHA.
<b>Benefits</b>	The accreditation or recognition program <b>enables employers to install equipment which has demonstrated compliance with applicable product test standards.</b> OSHA workplace inspections can also be expedited when certified equipment is used.
<b>Methodology</b>	Requires third party certification bodies to meet the strict criteria and requirements of competency and independence in 29 CFR 1910.7, including applicable international guides. Initial recognition is granted after the applicant completes a process that include: submission of a complete application; an on-site assessment; resolution by the applicant of deficiencies found during the assessment; publication of a preliminary notice in the <i>Federal Register</i> (FR) announcing the application for recognition, the proposed scope of recognition, the findings by OSHA, and any conditions of the recognition; a 60-day comment period; and then absent compelling reasons to the contrary, publication of a final FR notice to formally recognize the applicant as an NRTL.
<b>Testing</b>	Third party test/certification labs.
<b>Inspection</b>	OSHA inspectors can inspect equipment in the workplace.
<b>Conformity Identification</b>	Mark or label authorized by recognized NRTLs.
<b>Obligations of the Manufacturer/Vendor</b>	<b>Comply with applicable standards. NRTLs must use appropriate product safety standards in testing products;</b> test only products within their approved scope of recognition; and comply with other applicable requirements.
<b>Enforcement</b>	<b>Citation of employer for using uncertified equipment</b>
<b>Term</b>	Initial recognition is valid for 5 years
<b>Reciprocity</b>	Listing, labelling, or approval by foreign certification agencies is accepted by OSHA if the organization in question is recognized by OSHA as an NRTL. Eligibility for recognition of foreign organizations as NRTLs depends in part on whether the foreign countries are open to U.S. certifiers.
<b>Standards, Codes or Regulations</b>	<b>OSHA standards include</b> extensions of federal standards and federal and non-government standards incorporate reference. These include numerous standards of the American National Standards Institute, the American Society of Mechanical Engineers, the National Fire Protection Association, <b>Underwriters Laboratories, international standards</b> and guides, and others. OSHA standards are different from the product test standards used by the NRTL in certifying products.

## World Trade Organization – Compliance to Safety Standards

Compliance to Safety Standards are deemed to satisfy the Essential Safety Requirement

of the

LAW



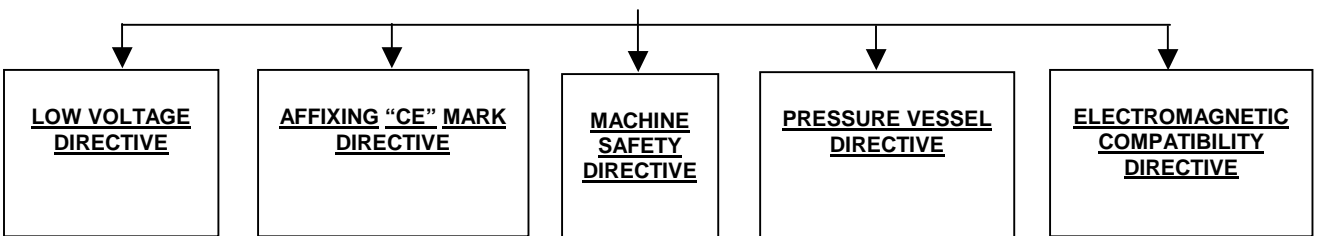
All Laws and Standards applicable to the safety of the product must be adhered to

## European Union – Compliance to Safety Standards

Compliance to European Norms are deemed to satisfy the Essential Safety Requirements

of the

**DIRECTIVES**



All Directives and Norms applicable to the safety of the product must be adhered to

## 6. 'New' Machine Safety Standards

### I. Light Curtain product standard: increases functional safety requirements

<b>IEC-61496 parts 1 &amp; 2</b>	WTO Requirement
<b>UL-61496 parts 1 &amp; 2</b>	USA Requirement – adopted (Aug '00)
<b>EU-61496 parts 1 &amp; 2</b>	EU Requirement * – (Fall '00)
<b>JIP-61496 parts 1 &amp; 2</b>	Japan Requirement – (Summer '00)
<b>BS-61496 parts 1 &amp; 2</b>	UK Requirement – (Spring '00)

Canada adopt by regulatory reference

Mexico adopt by regulatory reference to NAFTA

Europe adopt by inclusion in EN-292 as normative reference

**Note:** IEC-61496 is not the same as prEN-50100 (see "Light Curtain Marketplace Confusion" section)

### II. Safety system standard: functional safety requirements for entire safety system

<b>IEC-61508 parts 1 – 7</b>	WTO Requirement as of Feb '00
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#### Key Aspects of IEC-61508

- Functional Safety – ability of the safety system to perform its safety function over its life cycle
- Includes entire safety system and system defaults to the weakest link
- Safety Integrity Level – SIL
  - The probability of dangerous failure
    - $10^{-4}$  years .. 1 failure to danger in 10,000 years
    - High demand mode – greater than one demand of the safety system per year
- Separation of safety function from machine control function or else machine control function must have same SIL as safety function
- Diagnostic tests to discover faults within the safety system must be done at a rate significantly greater than the demand rate placed on the safety system

III. Light curtain application standard: applying light curtains to machinery to achieve safety

**IEC-62046**

release (winter '00)

**Key Aspects of IEC-62046**

- Guideline document to the Risk Assessment standard
- Considers:
  - Machine Characteristics
  - Protection Device Characteristics
  - Human Characteristics
  - Environmental Characteristics
- Takes into consideration overall lifecycle of machine i.e. degradation of machine stopping performance

IV. Risk Assessment: lifecycle analysis of machine hazards

**ISO-14121**

WTO Requirement ('99)

**ANSI-B11 TR 3**

USA Requirement (Fall '00)

**EN-1050**

EU Requirement ('97)

**Key Aspects of ISO-14121**

- Hazards are based on severity of injury
- Risk is based on frequency to the hazard
- Abatement is based on the safety integrity level of the protective device/measure

## 7.

### Light Curtain Marketplace Confusion

Much confusion exist in the marketplace as to what is the proper standard for light curtains. This is due to several light curtain manufacturers claiming compliance to EN-50100-1&2 and a few European Testing Laboratories issuing certification to prEN50100-1&2. The confusion is further perpetrated by manufacturers claiming prEN50100-1&2 is the same as IEC-61496-1&2 (see attached).

prEN50100-1&2 was stopped in development due to its inherent flaws.

- it was never a standard
- it will never be a standard

The standard that evolved is IEC-61496 parts 1&2. This standard is the Global baseline that is being adopted by the industrialized countries of the world as their national standard.

[see enclosed Major Differences between prEN50100-1&2 and IEC-61496-1&2]

3.

### Clauses Containing Safety Requirements

ISO/TS 16949  
Quality Management System for Automotive Suppliers

#### Quality System Requirements

Clauses	Clauses with "New" Safety Requirements
4.1 Management Responsibility	✓
4.2 Quality System	✓
4.3 Contract Review	✓
4.4 Design Control	✓
4.5 Document Data Control	✓
4.6 Purchasing	✓
4.7 Control of Customer – supplied product	
4.8 Product identification and trace ability	
4.9 Process Control	✓
4.10 Inspection and Testing	✓
4.11 Control of inspection, measuring and test equipment	
4.12 Inspection and test status	
4.13 Control of non-conforming product	✓
4.14 Corrective and preventive action	
4.15 Handling, storage, packaging, preservation and delivery	
4.16 Control of Quality Records	
4.17 Internal Quality Audits	✓
4.18 Training	
4.19 Servicing	
4.20 Statistical techniques	

## Quality Requirements

### 4.1 Management responsibility

#### 4.1.2.1.2 Customer representative

The supplier shall assign responsibility to appropriate individuals to represent the needs of the customer in internal functions in addressing quality requirements, such as selection of special characteristics

#### 4.1.2.1.3 Quality responsibility

Management with responsibility and authority for corrective action shall be promptly informed of products or processes which become noncompliant with specified requirements

#### 4.1.4 Business plan

The supplier shall utilize a formal documented, comprehensive business plan. The business plan shall be a controlled document

**Note:** This plan may typically include as applicable:  
- Health, safety and environmental issues

#### 4.1.7 impact on society

##### 4.1.7.1 Product safety

Due care regarding product safety means to minimize potential risks to employees, customers, users and the environment shall be addressed in the supplier's quality policy and practices, especially in design control (see 4.4) and process control (see 4.9) procedures and practices

##### 4.1.7.2 Regulations

The supplier shall have a process to ensure compliance with all applicable government, safety and environmental regulations

## Auditing Requirements

### Requirements

### What to Look For

Is authority delegated to personnel who have the organizational freedom to initiate action to prevent nonconformity occurrence?

Has the supplier assigned the responsibility to represent the needs of the customer in internal function?

Does the supplier utilize a controlled and comprehensive business plan that includes short-term goals and plan(s)?

Does the supplier's quality policy and practices address due care regarding product safety and means to minimize potential risks to employees, customers, users and the environment?

Does the supplier have a process to ensure compliance with all applicable government, safety and environmental regulations

- Responsibilities and authority as defined in job descriptions, responsibility matrices, procedures and accountability documents

- Quality function participation in milestones decision points

- Master List – reference to Business Plan
- Comprehensive, e.g. all business aspects, not just quality

- Preventive activities in design and process control
- Knowledge and application of legislation
- Risk analysis such as FMEA
- Results of internal/external audits including
  - System certifications
  - Corrective actions

- Process for government, safety and environmental regulations compliance

## Quality Requirements

### 4.2 Quality system

#### 4.2.3.2 Quality plan requirements

The supplier shall have a quality plan which includes customers' requirements and references to appropriate technical specifications

#### 4.2.4 Product realization

##### 4.2.4.4 Multidisciplinary approach

The supplier shall use a multidisciplinary approach to prepare for product realization, including:

- development/finalization of special characteristics,
- development, and review of FMEAs (see A.27) including actions to reduce potential risks,
- development and review of control plans.

The supplier shall carry out analysis of potential nonconformities and shall implement appropriate action. Process FMEAs shall include all special characteristics. Customers may have FMEA and control plan review and approval requirements which shall be observed.

##### 4.2.4.7 Special characteristics

The supplier shall apply appropriate methods to identify special characteristics (see annex C).

**Note 1:** Special characteristics may include product characteristics and process parameters.

All special characteristics shall be included in the control plan.

Annex C  
(informative)  
**Special characteristics**

Product characteristic or process parameter which affects a product's **safety or compliance with regulatory requirements.**

##### 4.2.4.9 Management of process design

###### 4.2.4.9.3 Process design input

The supplier shall identify, document and review the process design input requirements including:

- product design output data, such as design FMEAs,
- applicable regulations

###### 4.2.4.9.4 Process design output

The process design output shall include:

- process FMEAs
- process approval acceptance criteria
- methods of rapid detection and feedback of product/process nonconformities

#### 4.2.7 Process improvement

Continuous improvement shall extend to product characteristics and process parameters with the highest priority on special characteristics.

## Auditing Requirements

### Requirements

### What to Look For

Does the quality plan include the customer requirements and references to appropriate technical specifications?

- Technical specifications

Does the supplier convene multidisciplinary teams for planning the production of new or changed products including special characteristics, FMEA, and Control Plan?

- Personnel involved in definition of special characteristics, FMEA, and Control Plan

Are all special characteristics appropriately identified, complying with specific customer definition and included in the control plan?

- Process to establish special characteristics
- Design Record
- Review customer requirements for special characteristics, definitions and symbol identification
- Control plans

Are process control documents marked with the appropriate special characteristics symbol to indicate the steps that affect the special characteristics?

- Use of symbol to identify special characteristics in the process control documents for each process step

Are process design input requirements identified, documented and reviewed?

- Design FMEA

Does continuous improvement extend to product characteristics and process parameters with the highest priority on special characteristics?

- Records showing improvement in special characteristics

## Quality Requirements

### 4.3 Contract review

The supplier shall ensure that any customer-specific requirements are met [see also special characteristics]

### 4.4 Design control

The supplier's design output shall be the result of a process that includes:

- use of design FMEAs

### 4.5 Document and data control

The supplier shall establish and maintain documented procedures to control all documents and data that relate to the requirements of this International Standard including, to the extent applicable, documents of external origin such as standards and customer drawings.

The documents and data shall be reviewed and approved for adequacy by authorized personnel prior to issue. A master list or equivalent document control procedure identifying the current revision status of documents shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

This control shall ensure that:

- the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed;
- invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;

**Note:** An example of appropriate documents referred to in a) is:

- engineering standards

#### 4.5.2.2 Engineering specifications

The supplier shall establish a procedure to assure the timely review, distribution and implementation of all customer engineering standards/specifications and changes. The supplier shall maintain a record of the date on which each change is implemented in production (see 4.16). Implementation shall include updates to all appropriate documents.

**Note 1:** An appropriate unit of measure for “timely review” would be business “days”, not weeks or months.

## Auditing Requirements

### Requirements

### What to Look For

Does the customer ensure that all customer specific requirements are met?

- Process used to ensure that customer specific requirements are met

Has the design output been documented and expressed in terms that can be verified and validated against design input requirements:

- Identify Special Characteristics?

Was the design output a result of a process that included:

- Analysis of design failure mode and effects (DFMEA)?

- Design output records matching criteria established in design input requirements

Are all documents and data reviewed and approved by authorized personnel prior to issue? (4.5.2.1)

- Document approval authority
- Document approval records

Is there a master list (or equivalent) identifying document revision status readily available? (4.5.2.1)

- Master list or equivalent

Has the supplier established a process to ensure that pertinent issues of appropriate documents are available

- Document accessibility

Has the supplier established a process to ensure that invalid and/or obsolete documents are promptly removed

- Storage and disposal of obsolete documents

Is there timely review, distribution and implementation of customer engineering standards/specifications and changes?

- Process for notification/distribution of customer engineering standards changes

## Quality Requirements

### 4.6 Purchasing

The supplier shall establish and maintain documented procedures to ensure that purchased product (see 3.1) conforms to specified requirements

#### 4.6.1.3 Regulatory compliance

All purchased products or materials used in part manufacture shall satisfy current regulatory requirements applicable to the country of manufacture and sale such as environmental, electrical, electromagnetic, and safety.

### 4.9 Process control

The supplier shall identify and plan the production, installation and servicing processes which directly affect quality, and shall ensure that these processes are carried out under controlled conditions.

- c) compliance with reference standards/codes

### 4.13 Control of nonconforming product

The supplier shall establish and maintain documented procedures to ensure that a product that does not conform to specified requirements is prevented from unintended use or installation.

### 4.16 Control of quality records

The supplier shall establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance and disposition of quality records.

## Auditing Requirements

### Requirements

### What to Look For

Do all materials used in part manufacture conform to all applicable governmental, safety and environmental regulations as they apply to the country of manufacture and sale?

Do controlled conditions include compliance with reference standards

Are customer requirements for designation, documentation and control of Special Characteristics in compliance? Is documentation available?

Do process monitoring and job instructions include or reference

- Customer and supplier designated Special Characteristics?
- SPC requirements?
- Relevant engineering and manufacturing standards?

Does the control of nonconforming product and suspect material or product provide for identification, documentation, evaluation, segregation (when practical), disposition, and for notification of all appropriate functions?

Has the supplier defined the quality system related document and record retention periods to satisfy the minimum regulatory and customer requirements?

- Warrants or certificates of compliance

- Adherence to referenced standards, quality plans
- Tour of plant and facilities

- Designation and control of special characteristics
- Quality documents: control plan, specifications, drawings, etc. shall report the special characteristics designation

- Job instructions contents

- Obsolete products

- Defined record retention time compared to customer/regulatory requirements

## Quality Requirements

### 4.17 Internal quality audits

#### 4.17.2.3 Process audit

The supplier shall audit the product realization and production processes to determine the effectiveness of process performance (see A.43).

##### **A.43 Definition process audit**

onsite verification activity used to:

- verify that specified requirements for process capability/performance are met

#### 4.17.2.4 Product audit

The supplier shall audit products at appropriate stages of production and delivery to verify conformance to all specified requirements, such as product dimensions, packaging and labelling, at an appropriate frequency (see A.47)

##### **A.47 Definition product audit**

onsite verification activity used to :

- verify conformance to specified product requirements (e.g. design requirements, engineering specifications)

## Auditing Requirements

### Requirements

### What to Look For

Are product realization and production processes audited to determine the effectiveness of process performance?

- Audit plans
- Audit reports

Does the supplier perform product audits

- Audit plan, process flow chart and schedule
- Product audit procedure and reports

**Major Differences**  
prEN50100-1&2 vs IEC-61496-1&2

	<b>prEN50100-1&amp;2</b>	<b>IEC-61496-1&amp;2</b>
1) Safety Integrity Level <b>TYPE 4</b>	Ref catalog 4 of EN954-1  Redundancy	<ul style="list-style-type: none"> <li>• <b>Fault detection within response time</b> <ul style="list-style-type: none"> <li>– Redundancy</li> <li>– Automatic monitoring</li> <li>– Test optics and entire system for ability to change</li> <li>– Undetected faults (three deep)</li> <li>– Fault list Annex B changed variations not just 'on/off'</li> </ul> </li> </ul>
TYPE 2		Test input for optics & system test
2) Environmental EMC  Burst: Radiated RF: Surge: Induced Rf: ESD:	IEC-801-4 level 4 IEC-801-3 level 3 (none) (none) (none)	Add common cause fails (above)  IEC-61000-4-4 level 4 IEC-61000-4-3 <b>level x</b> IEC-61000-4-5 <b>level 4</b> IEC-61000-4-6 <b>level x</b> IEC-61000-4-2 <b>15 KV</b>  Test requirements changed also
Electrical Disturbances		Add: harmonics test
Ambient Light  AC Light Fluorescent Strobe DC Light Emitter Same	10,000 Lux No Value No Value 20,000 Lux No Failure to Danger  <b>Note:</b> Light aimed at white cardboard, reflected back toward receiver  <b>Note:</b> IR light penetrates paper	3,000 Lux <b>1,500 Lux</b> <b>200,000 Lux Peak</b> 3,000 Lux No Failure to Danger  <b>Note:</b> Light aimed at receiver
3) Misalignment	2° ± ½ " EAA	2 ½ ° EAA
4) <b>Redirecting Surfaces (Reflections)</b>	None	Immunity to redirecting surfaces <b>within 14.9 mm (.59")</b>
5) <b>Lable</b>	CE Mark	<b>Compliance to IEC-61496 and TYPE</b>



## QS-9000 Clauses Containing Safety Requirements

### 4.1 Management Responsibility

4.1.4 **Business Plan** includes “Health, **Safety** and Environmental Issues”.

### 4.2 Quality System Element

#### 4.2.3.4 Product Safety

“Due care and **product safety shall be considered** in the supplier’s design control (element 4.4) and process control (element 4.9) policies and practices. The supplier should promote internal awareness of safety considerations relative to the supplier’s product”.

#### 4.2.5.1 Continuous Improvement

“Continuous improvement shall extend to product characteristics with the priority on special characteristics”

Special characteristics are those key characteristics with safety or legal consideration.

### 4.3 Contract Review

4.3.2 “All customer requirements including those of Section II of this document shall be met”. (Section II specifies safety requirement).

### 4.4 Design Control

4.4.5 “Identify those characteristics that are crucial (special characteristics – See Appendix C) to the safe and proper functioning of the product”.

### 4.5 Document and Data Control

4.5.1 “**The supplier shall establish and maintain documented procedures to control all documents...including documents of external origin such as standards...**”

4.5.2 This control shall ensure that:

- a) “**the pertinent issues of appropriate documents are available...**”
- b) “**obsolete documents are properly removed...**”

### 4.6 Purchasing Element

4.6.1 “The supplier shall establish and maintain documented procedures to ensure that **purchased product conforms to specified requirements**”.

4.6.1.2 “All purchased materials used in part manufacture shall satisfy current governmental and safety constraints on restricted, toxic and hazardous materials; as well as environmental, electrical and electromagnetic considerations applicable for the country of manufacture and sale (see glossary – Approved Material)”

### 4.7 Control of customer supplied product

**Not applicable**

### 4.8 Product Identification and tractability

Not applicable

#### 4.9 **Process Control**

*Controlled conditions shall include the following:*

##### **Process Control**

b) *“use of suitable production, installation, servicing equipment, and a suitable working environment (see glossary)”*

c) *“compliance with reference standards/codes...”*

d) *“monitoring and control of suitable process parameters and product characteristics”*

*“Designation of Special Characteristics (i.e. safety considerations.) The supplier shall provide documentation showing compliance...”*

4.9.1 *“Process Monitoring and operator instructions shall include or reference, as appropriate:”*

- *“Relevant engineering and manufacturing standards”*

#### 4.10 **Inspection and Testing**

*“The supplier shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product are met”.*

#### 4.11 **Control of Inspection Measuring and Test Equipment**

*Not applicable*

#### 4.12 **Inspection and Test Status**

*Not applicable*

#### 4.13 **Control of Nonconforming Product**

*“The supplier shall establish and maintain documented procedures that product that does not conform to specified requirements is prevented from unintended use or installation”.*

#### 4.14 **Corrective and Preventive Action**

*“Any corrective or preventive action taken to eliminate the causes of actual or potential non-conformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered”.*

#### 4.15 **Handling**

*Not applicable*

#### 4.16 **Control of Quality Records**

*The supplier shall establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposition (DISPOSAL) of quality records.*

#### 4.17 **Internal Quality Audits**

*The supplier shall establish and maintain documented procedures for planning and implementing internal quality audits...*

#### 4.18 **Training**

*The supplier shall establish and maintain documented procedures for identifying training needs and provide for the training of all personnel...*

**4.19 Servicing**  
Not applicable

**4.20 Statistical Techniques**  
Not applicable

## Appendix I (Excerpts)

### 1. **General**

*These requirements are in addition to Appendices B, G, and H. They were developed from the latest issue of the IASG Sanctioned QS-9000 Interpretations at time of printing. Should additional sanctioned interpretations be published, they will be binding for registration.*

### 2. **Misrepresentation of Information**

*Misrepresentation of customer complaint information (for customers subscribing to QS-9000) by a supplier to a certification body/registrar shall result in the certification body/registrar immediately invoking their delisting process for that supplier and immediately notifying the customer (s) involved.*

### 30. **Auditing Safety, Health and Environmental Compliance**

*The supplier shall have knowledge of those requirements that are applicable and that the supplier have evidence of compliance to applicable requirements, but the third party QS-9000 auditor is not expected to conduct any type of compliance audit to these requirements.*

### 40. **Notification of Suspension**

*When a certification body/registrar places an existing QS-9000 registered company on a suspension because of non conformance or a violation of the rules of registration; the certification body/registrar shall notify, within 10 working days, each Chrysler/Ford/General Motors Supplier Quality Requirements Task Force representative of this action. These notifications are intended to remain confidential to the certification body/registrar, client, and the Chrysler, Ford, General Motors representatives.*

*This notification process is a requirement for all QS-9000 qualified certification bodies/registrars, and QS-9000 certified suppliers.*

## Glossary (Excerpts)

Approved Materials

**Approved Materials are materials governed either by industry standard specifications (e.g. SAE, ASTM, DIN, ISO) or by customer specifications.**