

A light gray world map is visible in the background, showing the outlines of continents and oceans.

Good Regulatory Practice

Standards And Conformity Assessment in Regulations

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Outline of Presentation

- **Industry Objectives and Process for Standards**
- **Conformity Assessment Process for the Construction and Mining Machines**
- **Good Regulatory Practices for the Use of Standards and Conformity Assessment in Regulations**



ISO Standards

- **Provide Information to Address Commercial and Safety Needs for Standardization:**
 - **Definitions and Terminology**
 - **Test Methods**
 - **Safety Performance Criteria**
 - **Conformity Assessment Process**
- **Developed by Global Experts**
- **Promote Global Harmonization**

Objectives for Machine Standards

- **Address All Safety Risks for Operators, Mechanics, and People Around Machines**
- **Define Performance Criteria, Not Design Specific, to Allow for Different Options and Improved Technology**
- **Define Reasonable and Realistic Performance Criteria, Adapted for Machine Applications**
- **Obtain Input From Machine Users, Health and Safety Experts, and Manufacturers**
- **Consider Sustainability for Standards**
 - **Social, Environment and Economical Factors**
 - **Support Sustainability for Machine Users**

Value of ISO Safety Standards

- **Define Acceptable Safety Levels**
 - **To Quantify Safety Expectations of Health And Safety Organizations and Machine Users**
 - **To Establish Acceptable Safety Levels for Machine Designers**
- **Establish a High Level of Safety To Allow Machines to Be Known as “Safe Machines”, Not “Hazardous Machines”**
- **To Enable Manufacturers to Self Declare Conformity to Standards and Regulations**
- **Promote Single Global Requirements**
 - **Common National Standards**
 - **Single Global Regulatory Requirements**

Conformity Assessment and Certification

- **Best Practice Is To Allow Manufacturers To Do Their Own Conformity Assessment Testing, Defined in ISO 17050-1 as Supplier's Declaration of Conformity (SDoc)**
- **ISO/TC 127 Standards Define Test Methods and Performance Criteria That Manufacturers Can Use For Conformity Assessment Testing and Certification**
- **Manufacturers Insure that Machines Comply With Standards and Regulations During the Development Process, Including the Replacement Parts for Machine Repairs**
- **Manufacturers Certify Machine Compliance**

Conformity Assessment and Certification

- **Some Countries Require Third Party Certification Because Manufacturers:**
 - **Do Not Have Expertise to Do SDoC**
 - **Do Not Have Test Facilities for SDoC**
- **Third Party Conformity Assessment and Certification Is Appropriate For These Countries**
- **The Long Term Goal Is SDoC, But Third Party Conformity Assessment and Certification May Be Necessary For the Short Term**
- **Testing Done By Manufacturers Should Be Accepted By the Third Party, If Properly Done**
- **No Additional Testing and Certification for Original Machine Replacement Parts Is Needed**

Conformity Assessment Testing

- **Conformity Assessment Testing Already Completed By the Manufacturer Should Be Accepted If the Manufacturer Has the Following:**
 - **A Quality Plan That Is at Least Equivalent to ISO 9000**
 - **A Documented Conformity Assessment Process**
 - **A Conformity Assessment Group/Person to Manage the Conformity Assessment**
 - **Access to Conformity Assessment Facilities (Manufacturers Facility or Independent Labs)**
 - **Documentation of Test Results**

Safety Regulations Using ISO Standards

- **Best Practice Is To Define The General Machine Safety Risks/Requirements In National Or Regional Regulations**
 - **EU Machine Safety Directive Is Good Example**
 - **USA Regulations Address General Safety**
- **Allow Regulations To Reference Or Use The National Or Regional Standards As The Technical Requirements For Safety**
 - **Adopt The ISO/TC 127 Standards As National Or Regional Standards (ISO 20474)**
 - **Allow Some Of The ISO Requirements in ISO 20474 To Be Voluntary In The Short Term for Developing Countries**

Summary

- **ISO Standards Can Be Used As the Basis for National Standards**
 - **A High Level of Reasonable and Realistic Safety Requirements Are Already Developed by Global Experts**
 - **Save Time and Resources by Using ISO Standards**
- **ISO Standards Can Be Used as the Technical Requirements for National Regulations to Promote Global Harmonization**
- **Helps Local Manufacturers Export Their Machines**
- **Benefits Local Machine Users with Machines that Have Higher Safety Standards**