Good Regulatory Practice

Standards And Conformity Assessment in Regulations

Dan Roley
Chair ISO/ TC 127
2015-06-02
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