Global Harmonization of Safety Standards

Examining the European influence on the practice of safety

By Fred A. Manuele

"ALMOST 99 PERCENT OF regulation will come from the European Union over time." Those are the words of Jeffrey Immelt, CEO of General Electric, as quoted in the April 23, 2002, issue of the *Wall Street Journal* (Mitchener). A safety director of a Fortune 100 entity recently said that his company had more lobbyists in Brussels, Belgium, than it did in Washington.

According to Michael Taubitz, whose safety responsibilities at General Motors are global, on policy-level issues, the Europeans have the organizations in place to bring together all stakeholders—government, employers, labor, suppliers, consumers and other interest groups. They also have developed processes through which these stakeholders can reach agreement on and issue standards and guidelines.

These statements prompted an inquiry to determine the extent to which standards and guidelines developed in Europe have affected the practice of safety and quality management in the U.S. and throughout the world, and how they may have an additional influence in the future.

The Path of Globalization

Global harmonization of safety, quality and environmental standards has progressed considerably. Prudent SH&E professionals must be aware of developments with respect to those standards and guidelines as they influence the expanding knowledge needs in the practice of safety. Several examples are cited here to illustrate how European activity on safety, quality and environmental standards impacts U.S.-based organizations and extends the knowledge needs of SH&E professionals.

Based on the author's evaluations and the committee work now in progress related to European safety standards and guidelines, the following predictions are offered.

1) The concept of safety through design will be moved forward by the adoption of ANSI standards containing provisions which will require equipment manufacturers to document that hazards have been identified and analyzed, and that risks have been reduced to an acceptable level.

2) It will become commonplace for equipment purchasers to develop detailed specifications for inherently safer designs to be implemented by design and engineering personnel in organizations that supply machinery and equipment.

3) Provisions requiring hazard identification and analysis, risk assessment and risk reduction will be included in standards pertaining to occupational safety and health management systems, and SH&E professionals will become skilled in those fields.

4) The value of including management of change (as now contained in OSHA's Process Safety Management standard) as

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an element in all safety and health management systems will be recognized.

5) As is the case in quality and environmental management, certified personnel independent of the employer will make accreditation audits of occupational safety and health management systems.

Safety in the Design Process

The central secretariat for the European Committee for Standardization is based in Brussels. It has attained consensus on many standards that member countries in the European Union (EU) are to apply. Three of those standards related to occupational safety and health have had considerable impact on manufacturers worldwide:

- European standard EN 292-1, Safety of Machinery—Basic Concepts, General Principles for Design. Part 1: Basic Terminology, Methodology. (EN stands for European Norm.)
- EN 292-2, Technical Principles.

These standards were issued in 1991. EN 292-1 required that designers of workplace machinery and equipment perform risk assessments and reduce the risks to tolerable levels. Since guidance was needed concerning what was expected in risk assessment, a third standard was issued in 1997—EN 1050, Safety of Machinery: Principles of Risk Assessment.

These three standards have been adopted—with some modifications—as international standards by the International Organization for Standardization (ISO). EN 1050 was adopted as ISO 14121 in 1999. EN 292 parts 1 and 2 became ISO 12100-1 and ISO 12100-2 in 2003. Titles of the standards remained the same.

ISO is the world's largest nongovernmental developer of standards, working with a network of the national standards institutes of 148 countries. The U.S. is represented at ISO by ANSI. A central secretariat based in Geneva, Switzerland, coordinates the system.

An early stated purpose of ISO was "to facilitate the international coordination and unification of industrial standards." Since its formation in 1947, ISO has issued more than 13,700 international standards. Although ISO standards are voluntary, countries have adopted them as part of their regulatory and administrative framework—particularly quality, safety and health, and environmental standards.

As of 1997, most of the machinery and equipment to be used in workplaces throughout the EU must bear a Compliance European (CE) mark. To obtain this mark, a "responsible person" (most often the manufacturer) must ensure that certain documentation concerning the product's safety is available for inspection by enforcement authorities. By affixing the CE mark, a manufacturer indicates that the product complies with all applicable directives in force—including the risk assessment and risk reduction provisions initially stated in EN 292-1 and included (with revisions) in ISO 12100-1. The CE mark is the passport for goods entering EU countries.

The provisions stated in ISO 12100-1 are intended for the designer. The standard defines the basic terminology and methodology designers are to use to achieve safety of machinery. It is a generic, all-encompassing standard with broad application. ISO 14121 provides guidance with respect to the risk assessment provisions in ISO 12100-1. These excerpts are from the scope of ISO 14121.

> This international standard gives guidance on the information required to allow risk assessments to be carried out. Procedures are described for identifying hazards and estimating and evaluating risk. The purpose of the international standard is to provide advice for decisions to be made on the safety of machinery and the type of documentation required to verify the risk assessment carried out.

Under the heading "Strategy for Risk Reduction," ISO 12100-1 states that the designer shall take the following actions—in this order:

- specify the machine's limits;
- identify the hazards and associated hazardous situations;
- estimate the risk for each identified hazard and hazardous situation;
- evaluate the risk and make decisions about the need for risk reduction;
- eliminate the hazard or reduce the risk associated with the hazards by protective measures.

Under the same heading, one finds extensive provisions for hazard identification, risk estimation and risk evaluation; hazard elimination or reduction via protective measures; and achievement of risk reduction objectives. ISO 14121 (Safety of Machinery: Principles of Risk Assessment) sets forth a hazard identification and risk assessment methodology.

All machinery and equipment that meets the definition of a machine in ISO 12100-1 which is exported to EU countries by American companies must meet the requirements of these standards. That trade encompasses many billions of dollars. To illustrate the extent of the impact of those standards, following is a review of actions taken by the ANSI committees responsible for standards pertaining to machine tools.

B11.TR3

ANSI's B11 Accredited Standards Committee (ASC) on Machine Tool Safety Standards formed a subcommittee to develop a technical report (TR) to provide guidance on the application of risk assessment principles for machine tool manufacturers and users. The committee's report (B11.TR3) is titled "Risk Assessment and Reduction: A Guideline to Estimate, Evaluate and Reduce Risks Associated with Machine Tools." TR3 became a registered ANSI document in November 2000. One guiding principle adopted by the committee was to produce a technical report that to the extent possible was harmonized with European standards.

B11.TR3 is a guideline for the committees responsible for the 24 machine tool standards administered by the B11 ASC. To date, revisions made in about 75 percent of those standards incorporate the risk assessment concepts set forth in TR3. Similar revisions are in progress for the remaining 25 percent.

Current Activity in the U.S. Related to European Standards

Minutes of the January 2005 meeting of the B11 ASC include this paragraph.

> The B11 ASC reiterates its intent to pursue adoption of the ISO standards 12100-1 and -2 (concerning general requirements for safety of machinery, including risk reduction) and 14121 (concerning risk assessment).

The B11 ASC is responsible for the ANSI standards pertaining to the design, construction, care and use of machine tools and for the technical reports that give the individual standards committees guidance on the specific subjects the reports cover. Assn. for Manufacturing Technology (AMT) is secretariat of the committee. Committee members have reported sensing a need to be more involved in the provisions of subsequent revisions of ISO standards that pertain to their products. If the three standards now being addressed are adopted as ANSI standards, the committee members believe they will have greater influence when the standards are next revised. Furthermore, as ANSI standards, they will have great influence on all machinery and equipment manufacturers, not just those making machine tools.

To repeat for emphasis, ISO 12100-1 is a generic, all-encompassing standard with broad application; it contains extensive requirements for hazard identification and analysis and risk assessment. Consider the long-term impact on the knowledge needs of SH&E professionals with respect to risk assessment if it becomes generally accepted that "the entry point for any safety improvement effort is the qualification and quantification of risk." If that occurs, a culture change will have occurred in the practice of safety.

The quote in the preceding paragraph appears in the notes of a PowerPoint presentation on Residual Risk Reduction (R3), a technique developed and issued by Liberty Mutual in 2004. These notes also state that the risk assessment technique recommended in the B11.TR3 was an inspiration in its development.

Similar language has also recently appeared in other documents. The Packaging Machinery Manufacturers Institute is secretariat of B155.1, Standard for Packaging and Packaging-Related Converting Machinery: Safety Requirements for Construction, Care and Use. Last issued in 2000, this standard is being revised. A review of the latest draft indicates that provisions will be extended with respect to identifying and analyzing hazards, assessing risks, applying a hierarchy of controls and reducing risks to an acceptable level over the life cycle of the packaging machinery. According to the foreword:

> This version of the standard has been harmonized with European (EN) and international (ISO) standards by the introduction of hazard identification and risk assessment as the principal method for analyzing hazards to personnel and achieving a level of acceptable risk.

Again, the European influence is noteworthy, and hazard identification and risk assessment are introduced as the principal methods to be used to achieve acceptable risk levels for personnel.

Another significant standard that will have impact on the content of the practice of safety is ANSI Z10, Occupational Health and Safety Management Systems. Approved in late July 2005, this standard was also influenced by European standards. The scope of Z10 is to develop a standard of management principles and systems to help organizations design and implement deliberate and documented approaches to continuously improve their occupational safety and health performance.

Because of the broad implications of an ANSI standard on occupational safety and health management systems, many companies and organizations have an interest in it. The introduction states:

> This . . . voluntary standard . . . uses recognized management principles in order to be compatible with quality and environmental management system standards such as the ISO 9000 and ISO 14000 series. The standard also draws from approaches used by the International Labor Organization's (ILO) Guidelines on Occupational Safety and Health Management Systems and from systems in use in organizations in the U.S.

ILO-OSH 2001

Reference in Z10 to the ILO-OSH Management Systems Guidelines is another indication of the progress of global harmonization on standards. ILO is a United Nations entity based in Geneva, Switzerland. Its governing body includes representatives of government, employers and worker organizations. Thirty-seven entities—including representatives from the U.S.—helped to develop these guidelines. It is unique in that it serves two purposes.

> The guidelines may be applied at two levels—national and organizational. At the national level, they provide for the establishment of a national framework for occupational safety and health management systems, preferably supported by national laws and regulations.
>
> At the organizational level, the guidelines encourage the integration of OSH management system elements as an important component of overall policy and management arrangements.

This is an exceptionally well-written, thorough and important document. It is, therefore, not surprising that it is referenced in ANSI Z10. Of particular note are its provisions on hazard prevention and risk assessment; management of change; emergency prevention, preparedness and response; procurement and contracting; performance monitoring and measurement; and audits—all of which are also addressed in Z10. The guidelines can be viewed at www.ilo.org/public/english/support/publ/xtextoh.htm.

The British Influence

In codes and standards with legal and enforcement status that include provisions for hazard iden-

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tification and analysis and risk assessment, it seems that the British have gone the furthest. The British Standards Institution (BSI) publication, Guide to Occupational Health and Safety Management Systems (BS 8800:1996), states that "the organization should carry out risk assessments including identification of hazards." An eight-page annex describes the risk assessment process.

In 1999, the U.K. Health and Safety Commission issued the Approved Code of Practice and Guidance, known as Management of Health and Safety at Work Regulations. This document has legal status. Its risk assessment requirements cover more than seven pages. Consider the specificity of the following language requiring that risk assessments be performed and to which employers the law applies.

> This regulation requires all employers and self-employed people to assess the risks to workers and any others who may be affected by their work or business. This will enable them to identify the measures they need to take to comply with health and safety law. Those who employ five or more employees should record the significant findings of that risk assessment.

OHSAS 18001:1999, Occupational Health and Safety Management Systems: Specifications, is not a standard. However, it has achieved the status of a quasi-standard in that some countries, particularly in Asia, expect employers to obtain certification indicating that their operations comply with its provisions. Many U.S. businesses are among those employers. In addition, there is a companion document designated as OHSAS 18002:2000, Occupational Health and Safety Management Systems: Guidelines for the Implementation of OHSAS 18001.

How did this guideline/quasi-standard and its companion piece emerge? According to an article in the June 2004 issue of *Occupational Hazards*, "A leading registrar argues that OHSAS 18001 is emerging as the standard of choice for companies seeking to implement a comprehensive safety management system." The leading registrar was BSI Management Systems, an independent third-party certification entity (O'Connell).

On two occasions—in 1996 and 2000—ISO voted on developing a standard for an occupational safety and health management system. Neither proposal was approved. The ISO membership is worldwide and a consensus for such a standard has not yet emerged among its membership.

Nevertheless, after the 1996 vote, BSI Management Systems assumed a leadership role and developed OHSAS 18001:1999. BSI Management Systems is a part of the BSI Group. One entity within that group is BSI British Standards, which is the national standards body of the U.K.

While it is clearly stated in OHSAS 18001 and 18002 that they are not British standards, OHSAS 18001 looks like a standard, is compatible with ISO quality and environmental standards, and has achieved considerable global success as the occupational safety management system for which certification is to be obtained. It has had a global impact. Of particular note is the extent of the requirements for hazard identification, risk assessment and risk control, and periodic safety management system audits. Wording in the audit requirements is similar to that in ISO's 14001 standard on environmental management.

Quality & Environmental Standards

Worldwide adoption of the ISO 9000 quality management and assurance standards and the ISO 14000 environmental management system standards indicate the progress of global harmonization of standards developed in Europe. These statements by ISO reflect the extent of the acceptance of those standards throughout the world.

> ISO 9000 and ISO 14000 standards are implemented by some 610,000 organizations in 160 countries. ISO 9000 has become an international reference for quality management requirements and ISO 14000 is well on the way to achieving as much, if not more, in enabling organizations to meet their environmental challenges.

ISO 9000

The ISO 9000 series was originally titled Quality Management and Quality Assurance Standard: Guideline for Selection and Use. The ISO 9000 series was adopted verbatim as an American National Standard—the ANSI/ASQ Q9000 series (ASQ is the American Society for Quality).

Companies worldwide have built their quality management systems around the ISO 9000 series. It has become common for purchasers of products and components to become a part of a purchaser's product to require that suppliers be certified as meeting the requirements of the ANSI/ISO quality standards.

For example, the Automotive Industry Action Group formed by DaimlerChrysler, Ford and General Motors has published quality system requirements (QS-9000) that are a close adaptation of the ISO 9000 series. All suppliers of automobile components to those companies must meet the quality system requirements contained in QS-9000. One of its provisions requires a supplier to conduct a failure modes and effects analysis on the components being supplied. Other industries have published adaptations of the ISO 9000 series as well.

Revisions to the ISO 9000 family of standards were approved as American National Standards in December 2000. The standard now has three parts:

- Q9000: Quality Management Systems—Fundamentals and Vocabulary;
- Q9001: Quality Management Systems—Requirements;
- Q9004: Quality Management Systems—Guidelines for Performance Improvement.

The original standard was designed principally for manufacturing companies and was based on 20 key quality management elements. Following a major revision, the standard is now structured on a process model. That change was made to accommodate any enterprise, regardless of its product or service or size.

ISO 14000

The ISO 14000 series contains 18 standards, two of which are relevant to this discussion.

1) ANSI/ISO 14001-1996, Environmental Management Systems: Specifications with Guidance for Use, sets forth the system elements required for effective environmental management. It is the conformance standard within the ISO 14000 series and it serves as the basis for auditing and certification.

2) ANSI/ISO 14004-1996, Environmental Management Systems: General Guidelines on Principles, Systems and Supporting Techniques, focuses on the development and execution of environmental management systems and their coordination with other management systems.

Joint sponsors ASC, American Society for Testing and Materials and NSF International obtained approval of these standards. (NSF describes itself as an independent, not-for-profit orgranization that offers programs to support the work of regulatory officials, including standards development. Services are also provided to companies, including quality and environmental management system audits and registrations). These standards, originating in Europe, have been adopted globally as the basis for obtaining certification on the adequacy of the environmental management system in place. Revisions in ISO 14001:2004 and ISO 14004:2004 were released on Nov. 15, 2004; they have not yet been adopted as ANSI standards.

Certification

The ISO quality and environmental standards require that periodic management system audits be performed. An example of the intent of an audit, as defined in ANSI/ISO 14001, follows:

> Environmental management system audit: a systematic and documented verification process of objectively obtaining and evaluating evidence to determine whether an organization's environmental management system conforms to the environmental management system audit criteria set by the organization, and for communication of the results of this process to management.

Requirements for quality management system audits in Q9001 are comparable. Both the quality and environmental standards state that the auditors must be objective and impartial. Governmental bodies and many other private organizations interpret this requirement to mean that the auditors should be external to the entity being audited. That does not mean the auditors must be from outside a company. An entity may self-declare conformance and have its internal staff perform the required audits.

Nevertheless, these audit requirements have spawned a new industry—a proliferation of companies which will perform the audits and certify that the location being audited is in conformance with the standards. Although ISO states that compliance certificates are not delivered on its behalf, having recognized a need to disseminate information on audit requirements and certifying bodies, ISO does have a directory of certification bodies.

SH&E professionals must recognize that these standards require periodic management system audits and that it has become globally accepted that they be conducted by independent certifying bodies. It should also be recognized that this auditing idea has been extended to an occupational health and safety management systems standard (ANSI Z10). Having safety management systems audited by third-party agencies and certified as being in compliance with a standard is in the future.

Related Documents

One reference used by writers of safety standards and guidelines is ISO/IEC Guide 51:1999, Safety Aspects: Guidelines for Their Inclusion in Standards. Its stated purpose is to provide standards writers with guidelines for the inclusion of safety aspects in standards. Pertinent sections include terms and definitions; use of the words *safety* and *safe*; concept of safety (there can be no absolute safety; residual risk; tolerable risk); and achieving tolerable risk.

ISO/IEC Guide 73:2002, Risk Management: Vocabulary—Guidelines for Use in Standards, is a companion to Guide 51. According to the introduction, "this guide is intended to be used as a top-level generic document in the preparation or revision of standards that include aspects of risk management." These guides were jointly developed by ISO and International Electrotechnical Commission (IEC). Their forewords note that ISO and IEC form the specialized system for worldwide standardization. IEC is a global organization that publishes international standards for all electrical, electronic and related technologies. Many of those standards have safety implications as well. IEC's central office is also in Geneva.

Conclusion

Safety-related standards and guidelines originating in Europe have had—and will continue to have—a prominent global influence on the practice of safety. Affected U.S. entities must become more involved in their initiation and revision. Some entities have begun to do so. For example, ORC Worldwide (formerly known as Organization Resources Counselors), of which about 125 Fortune 500 companies are members, has formed an emerging issues committee that gathers and distributes information.

ASSE and ORC Worldwide are among those groups that have encouraged OSHA to take a more active role in standards-writing that has global influence. The March 2005 Government Affairs column in *Professional Safety* reports that "ASSE would also like

More on Globalization

More information on this subject is available at http://europa.eu.int/eur-lex/en/com/pdf/2002/com2002_0118en01.pdf. This document is a 2002 communication from the Commission of the European Communities titled "Adapting to Change in Work and Society: A New Community Strategy on Health and Safety at Work 2002-06."

Another helpful reference on European Standards is available at http://ts.nist.gov/ts/htdocs/210/gsig/eu-guides/sp951/text-sp951.htm. This National Institute of Standards and Technology (NIST) publication is titled, "NIST Special Publication 951: A Guide to EU Standards and Conformity Assessment."

Web Links to Key European Agencies

British Standards Institution (BSI)
www.bsi-global.com/News/Contacts/index.xalter

BSI Management Systems
www.bsi-global.com/News/Information/Management+Systems.xalter

Commission of the European Communities
http://europa.eu.int/eur-lex/en/com/pdf/2002/com2002_0118en01.pdf

European Union
www.eurunion.org/infores/resguide.htm

European Community for Standardization
www.cenorm.be/cenorm/index.htm

U.K. Health & Safety Commission
www.hse.gov.uk

International Electrotechnical Commission
www.iec.ch/about/co/office-e.htm

International Labor Organization
www.ilo.org/public/english/support/publ/xtextoh.htm

International Organization for Standardization
www.iso.org

OSHA to establish and provide the needed proactive leadership to help ensure that U.S. safety and health efforts are harmonized with efforts around the globe. This could be a great new area for OSHA to advance safety and health and ensure competitiveness for U.S. companies."

In an Internet article titled, "The New Global Drivers of Workplace Safety and Health: Will OSHA and U.S. Business Help Steer or Just Be Along for the Ride?" ORC Worldwide states:

> ORC believes strongly that all stakeholders in the U.S. occupational safety and health community must find new strategies and resources to become more fully engaged in the global policy debates over initiatives that are likely to affect the safety and health of workers in the U.S., as well as workers abroad. ORC also believes that OSHA, as the institution at the "point" of occupational safety and health policy in the U.S., should lead the way . . . and help facilitate increased engagement of other U.S. stakeholders in these debates (www.orcworldwide.com).

It is proposed that OSHA take on an extended role—which some may view as difficult to achieve. Nevertheless, it is appropriate to suggest that OSHA be more involved in the global policy debates on SH&E standards and guidelines.

One must also ask whether, as a service to its members, ASSE should take a more aggressive and proactive role, particularly on information gathering and distribution. It is an obvious fact that considerable progress has been made in the global standardization and harmonization of safety, quality and environmental standards and new developments will continue to emerge. SH&E professionals must be aware of developments with respect to those standards and guidelines—which will expand the knowledge needs in the practice of safety.

This article relates principally to safety, quality and environmental management systems, and to hazard identification and analysis and risk assessment, of which superior knowledge and proficiency is needed to move the state of the art forward in the practice of safety. However, as Michael Taubitz suggests, Americans need to be attentive to the emergence in Europe of discussions about issues such as corporate social responsibility, quality of work, mainstreaming the gender dimension (women in the workplace) into risk evaluation, reducing psychosocial risks (stress, depression and anxiety due to workload or environment), systems for classification and labeling chemical materials (reach), and enhanced prevention of occupational illnesses. ■

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