

MANAGEMENT AND POLICY

DEVELOPMENT OF AN ISO 9000 COMPATIBLE OCCUPATIONAL HEALTH STANDARD: DEFINING THE ISSUES

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Corporate ISO 9000 registration is gaining international acceptance as the hallmark of quality system achievement. The International Organization for Standardization (ISO) is currently drafting environmental standards that will complement ISO 9000. Should the international community also consider development of an ISO 9000-compatible occupational safety and health management standard (OSHMS)? To determine the advantages and disadvantages of this issue, the investigators conducted interviews with government and private sector experts, reviewed publicly accessible ISO documents, and evaluated published literature germane to the subject. Major advantages of an ISO OSHMS were the harmonization of national standards, maximizing Occupational Safety and Health Administration (OSHA) efficiency through third-party registration audits, and increased emphasis on employee-driven health and safety programs. Major disadvantages were the single vote of the American National Standards Institute at international proceedings, direct and indirect program development costs, potential unethical or incompetent conduct of registrars, and the logistics of developing an acceptable standard to all stakeholders. Some unresolved issues were the inevitability of an ISO OSHMS, auditor indemnification, and the scope of OSHA participation. Industrial health and safety professionals should initiate formal discussion on this issue to elaborate on findings presented here and to establish a consensus on future activities.

The International Organization for Standardization (ISO) published the 9000 Series of Quality System Management Standards in 1987. Roughly 25,000 manufacturing sites in Europe and North America have received ISO 9000 registration since that time.^(1,2) The ISO Technical Committee for Environmental Management (TC-207) is currently drafting additional standards that will apply to environmental aspects of corporate operations. These draft standards have received the 14000 series designation and encompass environmental

management systems, environmental performance evaluation, and life cycle assessment, among other related matters.⁽³⁾ In parallel with these developments, private and public sector professionals have initiated discussion on the merits of developing an international occupational safety and health management standard (OSHMS) that theoretically would complement the existing 9000 and 14000 series standards.^(4,5)

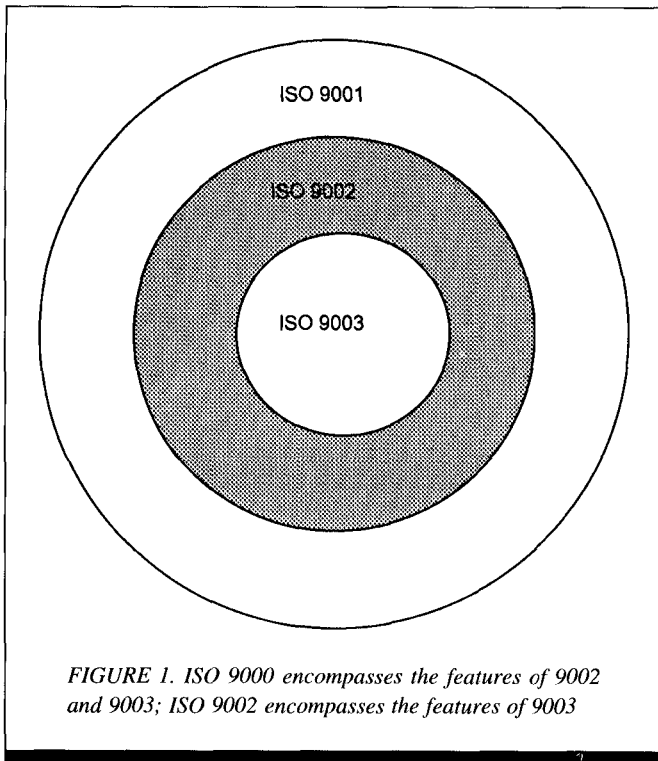
The purpose of our research was to evaluate the advantages and disadvantages of developing an ISO compatible OSHMS, including the integral issue of third-party verification of occupational hygiene and safety program adequacy. The authors conducted literature reviews and interviewed ISO experts from labor, government, academia, and private industry. Internal technical committee and ISO documents were reviewed. The findings are presented in historical context to provide the reader with salient background information.

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

ISO, a nongovernmental organization headquartered in Geneva, Switzerland, was created in 1946 to promote the development of international standards. These standards were intended, in large measure, to facilitate global trade by harmonizing dissimilar national standards.⁽⁶⁾ The organization's initial emphasis was on ensuring a measure of conformity for goods and services provided in international commerce. Approximately 90 member nations, representing 95% of the world's industrial capacity, participate in the ISO standards-making process.⁽⁷⁾ Each member nation is empowered with a single voting delegate. The American representative to ISO is the American National Standards Institute (ANSI).

ISO 9000

ISO has various technical committees that develop, through international consensus, international standards or guides. ISO Technical Committee 176 was established in 1979 to develop



quality system standards. This particular standard development process culminated eight years later, in 1987, when ISO published five international quality system standards (ISO 9000, 9001, 9002, 9003, and 9004).⁽⁸⁾ It is this series that recently has received considerable attention from the public and private sector alike.

The ISO 9000 quality system standards encourage companies to implement quality management and quality assurance systems. These systems, which ultimately are intended to improve products or services, do not specifically apply to the products or services themselves. Rather, the ISO 9000 standards apply to the production systems.

A fundamental feature of the ISO 9000 standards is their generalizability. They can be used as a tool to evaluate the system performance of virtually any activity in virtually any industry. This approach ensures that the quality systems required for conformance with the standard will accommodate any level of technical sophistication and not bias against small firms or those who do not possess state-of-the-art technology. The flexibility inherent in the standards also allows maximum accommodation of philosophical approaches to quality systems. Simply put, these verification standards determine if a company is performing consistently. The standards do not specify how a company must conduct its business.

The five ISO 9000 series standards are unique but complementary.⁽⁶⁾ ISO 9000 and 9004 are guidance documents. ISO 9000 advises potential users about the distinction between and the selection and use of the five different 9000 series standards. Standard 9004 provides guidelines for quality management and quality system elements. In other words, the 9004 document provides corporate managers with assistance in the development of a quality system. For those new to ISO jargon, ISO also produced

the Quality-Vocabulary Standard (ISO 8402), which provides definitions for ISO quality-related terms.⁽⁹⁾

The actual performance standards, ISO 9001, 9002, and 9003, represent varying degrees of achievement in quality system performance (Figure 1). ISO 9001 is the most extensive and ambitious standard. It encompasses quality systems assurance in design/development, production, installation, and servicing. ISO 9002 is slightly less comprehensive. Its application is focused primarily on quality assurance in production and installation. ISO 9003 is limited to quality assurance in final inspection and testing. When companies claim they are "ISO 9000 registered," they have achieved registration under 9001, 9002, or 9003. ISO 9000 registration status is provided on a site-by-site basis or for a specific business unit within a particular company. Registration is not provided company-wide based on successful registration at one location.

Although there is no standardized process for acquiring ISO registration, some basic steps generally are conducted during the ISO 9000 application process. These steps typically are as follows.⁽¹⁰⁾

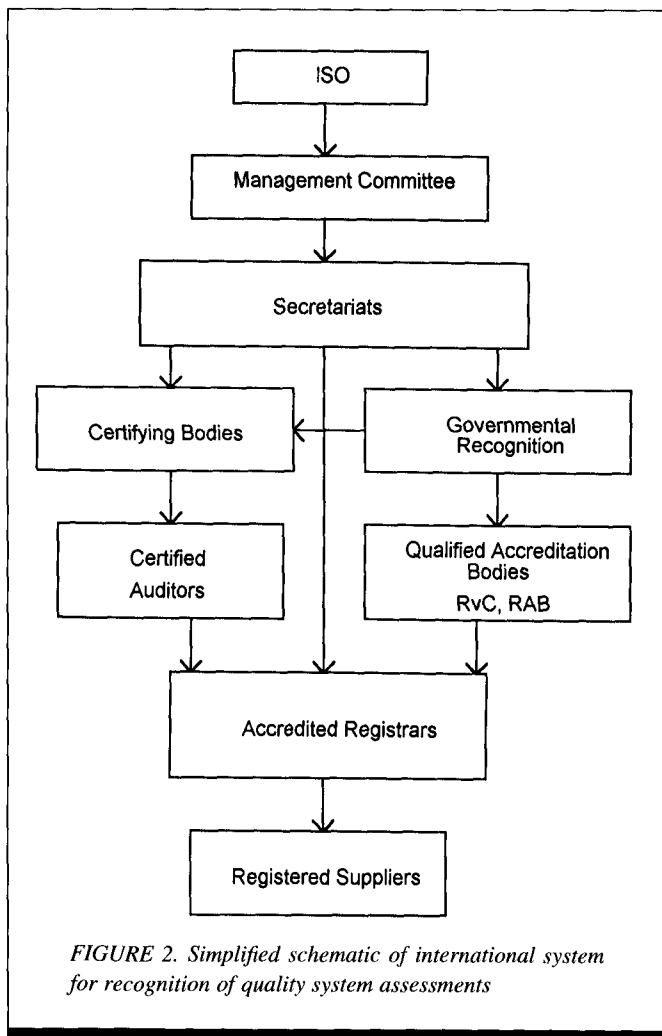
Step 1: Once a decision is made to pursue ISO registration, the company (referred to as the "supplier" by ISO) submits a completed application that details the quality management system implemented at the site. This application is submitted directly to an accredited registrar selected by the applicant company itself. In the United States a list of U.S. accredited registrars can be obtained from the Registration Accreditation Board (RAB), an affiliate organization of ANSI.⁽¹¹⁾ (A further description of registrars will be provided later in this section.)

Step 2: The Registrar conducts a desk audit of the application material. This step generally will detect potential problems with the application or reported quality system.

Step 3: A single auditor from the registrar's company will then conduct a preassessment site visit to gather supplemental

TABLE I. Scope of ISO 9001 Field Audit

- 1) Management Responsibility
- 2) Contract Review
- 3) Document Control
- 4) Purchaser Supplied Product
- 5) Process Control
- 6) Inspection, Measuring, and Test Equipment
- 7) Control of Nonconforming Product
- 8) Handling, Storage Packaging, and Delivery
- 9) Internal Quality Audits
- 10) Servicing
- 11) Quality System
- 12) Design Control
- 13) Purchasing
- 14) Product Identification and Traceability
- 15) Inspection and Testing
- 16) Inspection and Test Status
- 17) Corrective Action
- 18) Quality Records
- 19) Training
- 20) Statistical Techniques



information that may have been absent in the original application or to clarify substantive issues.

Step 4: A full complement of auditors either hired or retained by the registrar confirm conformance with the respective ISO 9000 standard. This is achieved by reviewing company documents and evaluating site operations during a thorough three- to five-day site audit. The site review verifies that the quality system reported on paper is being effectively implemented throughout all levels of the organization. Table I presents the scope of the ISO 9001 field audit.

Step 5: A decision is made by the registrar's management, not the site audit team itself, to award or deny ISO 9000 registration to the site. The site is reaudited every six months, through announced and unannounced site visits.⁽¹²⁾ For very small companies, annual inspections can be arranged.⁽¹⁰⁾

The applicant company pays for all expenses associated with the application review and site visit. Direct costs for site registration evaluations range from \$10,000–\$30,000.^(2,13) Indirect costs vary and are a function of the company's existing quality system sophistication. In-house expenses may exceed \$100,000 for programs developed from scratch.⁽¹⁴⁾

A critical function in the ISO 9000 registration process is provided by the registrar. Registrars are generally independent third-party corporations/companies that have

demonstrated knowledge and expertise in ISO 9000 and its application to a particular industrial sector. Those companies that demonstrate expertise as outlined in ANSI Z34.1, Third Party Certification for Programs and Services, receive accreditation from the RAB.^(6,11) Once a company achieves accredited registrar status, they may in turn approve individual industrial or commercial operations for ISO 9000 registration.

RAB, together with ANSI, manages the American National Accreditation Program for Registrars of Quality Systems. This is the program that grants "accredited" status, as outlined in ANSI Z34.1, for consulting organizations that wish to offer registration services. There are 24 RAB-accredited registrars and 9 pending applications in the United States.⁽¹¹⁾

Accredited registrars are in turn audited by RAB to ensure they are doing their work appropriately and consistently. RAB accredits registrars within the United States. Foreign accrediting bodies, such as the Dutch Raad voor de Certificate (RvC); the Standards Council of Canada and others may also accredit registrars.⁽⁸⁾ Foreign accredited registrars also may provide registration services in the United States. An overview illustrating the ISO accreditation body-registrar-supplier relationship is presented in Figure 2.

Quality assurance is not limited to the standards and registrars. ISO also provides a 10,000 series of guidelines that provides guidance in the conduct of auditing quality systems, minimum auditor qualifications, and the actual management of audit programs. These guidelines, much like the standards, are performance based.

The annex of ISO 10,011–2 provides direction for evaluating potential auditors.⁽¹⁵⁾ Auditors are required to show evidence of having necessary knowledge to carry out or manage the audit. The basics skills to be an ISO 9000 auditor include appropriate education, auditing training, experience, sound personal attributes, management capabilities, maintenance of competence in quality systems, and language skills.

ISO also suggests that auditors prove technical adequacy by passing an examination administered by a national certification body. An example of such a body is the American Board of Industrial Hygiene.

What are the corporate benefits of obtaining ISO 9000 registration? Most ISO 9000 registered companies claim that significant organizational improvements are achieved by submitting to the rigorous registration process. Surveys conducted by the British government and Lloyd's Register Quality Assurance Ltd. state that 89% of ISO 9000 registered companies reported greater operational efficiency; 83% reported improvement in management control; 63% reported improvements in marketing; and 26% reported improved export sales.⁽¹⁶⁾ Some also are suggesting ISO 9000 registration may be necessary in the future to conduct business in the European Economic Community (EEC).⁽¹⁷⁾ There are already seven European Community industries where suppliers must have ISO 9000 certification or a registered quality system.^(18–19)

To date approximately 74 countries have adopted the ISO 9000 series standards.⁽²⁾ These include most of the industrialized world including the United States, Canada, Australia, most of Asia, South America, and all of the European Community. The

major exceptions appear to be a substantial number of countries on the African continent.

Western Europe has approximately 20,000 manufacturing sites that are ISO 9000 registered.⁽¹⁾ This compares to the roughly 3600 registered sites in the United States and Canada.⁽²⁾ Even though there are fewer registered companies in the United States, large multinational firms such as Ford, Chrysler, General Motors, IBM, Xerox, and Motorola reportedly favor ISO 9000-registered vendors or employ ISO-type audits while evaluating suppliers.⁽¹⁾

The Big Three U.S. auto makers also have collaborated in the publication of a draft document, *Quality System Requirements* (QSR), which details the quality expectations of their respective internal and external suppliers. As such, each supplier must incorporate the quality system described in the document into its own quality manual. ISO 9001, Section 4, was adopted as the foundation of the Big Three's quality document.⁽²⁰⁾ Suppliers located in countries from the industrialized, newly industrialized, and developing segments of the world economy all participate in the QSR program.

ISO Environmental Standards

In partial response to the June 1992 United Nations Conference on Environment and Development, ISO established TC-207 to develop international environmental consensus standards known commonly as the 14000 series. Although third-party verification will likely be limited for most of the proposed standards as currently drafted, participating companies will likely have to develop or document systems that are pertinent to environmentally related management systems, performance evaluations, auditing, product labeling, and life cycle assessment.⁽²¹⁾ TC-207 also will develop a terms and definitions standard (similar in scope to ISO 8402) and a guide for environmental aspects in product standards.

Technical Committee 207, through its various subcommittees, already has achieved considerable progress toward completing many of the standards noted above.⁽³⁾ The Canadian Standards Association also has completed the first three phases of its own environmental management systems (EMS) pilot program.⁽²²⁾ The Canadian program has recruited 20 companies to benchmark their respective EMSs to the draft ISO standard. In addition, U.S.-based NSF International (formally known as the National Sanitation Foundation) has completed its own EMS specification document (NSF 110), which is the new voluntary national EMS standard.⁽²²⁾ Like the Canadian document, NSF 110 also will complement the counterpart ISO standard. NSF International also is initiating a pilot program to test its EMS and is inviting businesses to participate.

U.S. Federal ISO 9000 Activities

Adherence to nongovernmental consensus standards is not a phenomenon strictly limited to the private sector. In October 1993 the federal Office of Management and Budget published Revised OMB Circular A-119.⁽²³⁾ This document provides federal agencies with guidance on use of private standards and participation in voluntary standards bodies and standards developing groups. It states that "participation by knowledgeable

agency employees in the standards activities of voluntary standards bodies and standards-developing groups, both domestic and international, should be actively encouraged and promoted by agency officials."

The circular also provides insight on potential utility of consensus standards. "Participation by agency representatives should be aimed at contributing to the development of voluntary standards that . . . will eliminate the necessity for development or maintenance of separate government standards," it states. The OMB document also supports direct financial, administrative, technical assistance, and joint planning with technical bodies.

Many federal agencies already are implementing ISO 9000 or are in the process of evaluating its potential. The Food and Drug Administration, Department of Defense, the National Aeronautics and Space Administration (NASA), the Federal Aviation Administration, National Institute for Occupational Safety and Health (NIOSH), Department of Education, and others are currently exploring the possible applications of ISO 9000 to their respective agencies.⁽²⁴⁻²⁷⁾ The Interagency Committee on Standards Policy serves as a clearinghouse for the dissemination of federal ISO 9000 activities.

Government Considers Role of Independent Third-Party Verification

Published articles already have suggested a logical linkage between ISO 9000 Series standards and occupational safety and health.^(1,28) *The Occupational Safety and Health Reporter* quoted assistant secretary of labor for the Occupational Safety and Health Administration (OSHA) Joe Dear as calling the ISO standards "major leverage" for workplace health and safety improvement.⁽⁴⁾ As noted earlier, the accredited registrar plays a major role in the awarding of ISO 9000 registration. Independent third-party verification of occupational hygiene program adequacy also has been promoted by the Clinton administration as a possible mechanism to assist OSHA in achieving its mission.⁽²⁹⁾

The third-party verification issue was raised formally at the federal level by the 1993 Vice Presidential Report of the National Performance Review.⁽²⁹⁾ The report recommended that "the Secretary of Labor . . . issue new regulations for worksite safety and health, relying on private inspection companies or nonmanagement employees." Joe Dear continued the discussion during a May 1994 keynote address to the American Industrial Hygiene Conference.⁽³⁰⁾ During his speech, Dear posed the questions "if we were to have independent third parties certify work places, who would do the certifications? What would be their qualifications? How would we ensure program integrity? What incentives could be developed to move in that direction?"

The body of evidence that has prompted the federal sector to examine and debate the third-party verification issue is compelling. Approximately 2400 federal and state industrial health inspectors are currently employed to safeguard some 93 million employees at 6.2 million U.S. worksites.⁽²⁹⁾ According to these figures, the U.S. inspector-worksites ratio is approximately 1:2583. Clarence Crawford's (U.S. General Accounting Office) October 1993 testimony to the U.S. House of Representatives Subcommittee on Labor Standards (Occupational Health and

Safety) reported the ratio to be 1:3000.⁽³¹⁾ In any event, the seminal issue is the disparity between safety and health enforcement staffing levels and the immense number of worksites that currently exist in the United States.

One method of assisting OSHA in meeting its personnel requirements is retaining noncompensated special government employees or SGEs. Federal OSHA's Office of Cooperative Programs has used SGEs in support of their Voluntary Protection Programs (VPP).⁽³²⁾ The SGEs are unpaid third-party health and safety professionals who assist OSHA during site reviews. The VPP model is mentioned as a possible companion to a future ISO-based OSHMS. Therefore, a further description of the program is presented.

Third-Party Participation under the VPP Model

The precursor of the federal VPP was developed, ironically, in 1978 as a repercussion of bogus labor complaints lodged with the California Occupational Safety and Health Administration (CAL/OSHA) from employees at the San Onofre Nuclear Power Plant construction site.⁽³³⁾ Anonymous phone calls alleging workplace health infractions resulted in 12 CAL/OSHA inspections, which ultimately generated only a single citation. Both labor and the general contractor, Bechtel Corporation, concluded that an on-site labor-management committee could handle inspections and complaints. CAL/OSHA could therefore focus their limited resources on truly hazardous worksites.

An agreement between the California Department of Occupational Health and Safety, Bechtel Corporation, the National Constructors Association, and the California Construction Trades Council resulted in an experimental program called the Voluntary Self Inspection Program (VSIP). The underlying purpose of the agreement was to transfer responsibility for the enforcement of OSHA rules from CAL/OSHA to a joint labor-management committee at the worksite.

A similar program loosely based on the California model was implemented at the federal level in 1982. The major purpose of the program, now called the Voluntary Protection Programs, was to provide recognition for companies who voluntarily exceeded baseline federal and state health and safety standards. Incentives were developed to encourage employer participation.

A brief synopsis of the VPP application procedure is as follows:⁽³⁴⁾

- (1) Businesses interested in program participation submit a formal application package to the appropriate regional OSHA office. This application provides the agency with a broad spectrum of information on the employer's health and safety program. The applicant's submission subsequently is reviewed and if satisfactory, a site visit is scheduled.
- (2) OSHA personnel then conduct a three- to five-day on-site review of the facility. (It is important to note that if OSHA compliance personnel are used for the site review, they may not come from the same geographical jurisdiction as the site location.) The inspection team verifies occupational hygiene program adequacy in the

following six areas: management commitment and planning, worksite analysis, hazard prevention and control, safety and health training, employee involvement in program evaluation, and annual evaluation of the safety and health program. The site review team balances all available site information, including employee interviews, to determine if systematic management procedures that address hazard assessment, prevention, and control are being effectively implemented. Those sites that successfully pass the intensive site and record keeping evaluation process also must achieve another level of success. The companies must over the three years preceding the site inspection maintain an average of lost workdays and injury case incidence at or below the rates of the most specific industry national average (by standard industrial classification, i.e., SIC code) published by the Bureau of Labor Statistics.

- (3) The site review team's findings are reviewed by OSHA management personnel, who typically were not involved with the actual review. This administrative review is the last step in the process. Those satisfying the above requirements become VPP "Participants."⁽³⁴⁾
- (4) The firm's management receives a letter from the assistant secretary of labor congratulating them on being awarded VPP status. Furthermore, these companies are "rewarded" by receiving immunity from programmed OSHA inspections. OSHA may still inspect VPP sites in response to employee complaints, fatalities, significant chemical releases, or catastrophes. Most sites are re-evaluated every three years to ensure that good management practices are continued, and there is continuous improvement.

It is also important to note that there is a hierarchy of VPP achievement, with the designations Star, Merit, and Demonstration. Sites awarded Star status generally have safety and health programs recognized as comprehensive and effective. The Merit designation is provided to those worksites with the potential to be Star but that may have some minor health and safety program elements to be corrected. For example, OSHA may elect to give Merit status to a company with an overall good health and safety program but whose illness and injury rates have yet to drop below national averages. The third award is the Demonstration designation. Demonstration status may be awarded to companies that are not construction or general industry oriented, such as maritime or agriculture businesses. Star and Demonstration sites receive annual onsite reviews.

As with most accreditation-type site visits, financial costs and company time commitments are subject to the pre-existing level of site preparation for the VPP review. Most VPP site approval visits generally last three to five days. Site review team expenses, including direct and indirect costs, are estimated to be \$6700-\$7000 per inspection team. These fees are underwritten by OSHA.⁽³⁵⁾

As of September 1994 there were approximately 195 sites approved to participate in VPP.⁽³⁶⁾ An additional 60 to 70 backlogged applications had been received and were waiting to be

processed.⁽³⁵⁾ VPP's annual budget generally ranges from 1.6 to 1.8 million dollars.⁽³⁷⁾

VPP participant companies include chemicals, construction, food processing, hospitals, manufacturing, medical research, meat, plastics, refineries, textiles, storage and distribution, wood and paper products, as well as research and development. One third of employees at VPP sites are represented by a collective bargaining agent.⁽³⁸⁾ The Voluntary Protection Programs Participant's Association (VPPPA) reports that their member companies' average injury incidence rates between 60–80% below respective standard industrial classifications.

Another distinctive aspect of VPP is its current gravitation toward using SGEs or independent third-party participants in VPP site reviews. Pursuant to the provisions of Section 7(c)(2) of the Occupational Safety and Health Act, the assistant secretary for labor is authorized to "employ experts and consultants or organizations." OSHA is using this clause to retain the services of SGEs in support of VPP.

These SGEs are volunteers from general industry who assist OSHA personnel during VPP worksite reviews. The rationale for using nongovernmental personnel appears sensible. Every three- to five-day VPP site evaluation may use OSHA compliance personnel who might otherwise be inspecting truly hazardous worksites.⁽³⁹⁾ Each SGE substitute theoretically frees a federal inspector from VPP duty.

The first trial exercise using a noncompensated SGE occurred in February 1994 at an AT&T site in Orlando, Fla. A VPP site approval audit was conducted by three OSHA personnel and one SGE, a full-time Monsanto employee. Two additional sites had been inspected by VPP audit teams using SGEs at the time of this document's submission.

A critical question regarding the competency and expertise of SGEs has been addressed by OSHA. A draft version of VPP SGE requirements was made available to the authors. An SGE must currently be a health/safety professional; have two years' related experience; be from a current VPP site; successfully participate in OSHA's safety and health program assessment training course; be actively involved in securing or maintaining VPP status; have a basic knowledge in applying OSHA regulations; have positive interpersonal skills; have basic writing skills; be physically able to perform work; and be recommended by management.

OSHA is not the only federal agency using third parties to assist in voluntary inspections. The Department of Energy (DOE) recently designed their own version of VPP and approved its first Star site in October of 1994.⁽⁴⁰⁾ Minimum qualifications to participate as a third-party DOE VPP site evaluation audit team member have not been formalized to the extent of federal OSHA's, but do include appropriate experience and specific training requirements.⁽⁴¹⁾ Federal OSHA has provided guidance to DOE regarding development and implementation of VPP to the extent that a formal relationship establishing this fact was consummated early in 1994.⁽⁴²⁾

DOE and OSHA reached an agreement that was signed by David Zeigler, director of the Directorate of Administrative Programs, OSHA; and Joseph Fitzgerald, Jr., deputy assistant secretary for safety and quality assurance, DOE. The purpose of this alliance was to assist DOE in the development of its own

DOE-VPP at government-owned/leased contractor operated facilities. In return DOE was to provide general support to OSHA. The agreement went into effect January 25, 1994, and is to last three years.

Federal OSHA uses third parties in support of many of its programs. These include the NRTL program, the Gear Certification program, Blood Laboratory Certification Program, the new asbestos standard, corporate-wide settlement agreements, and the Consultation Safety and Health Program Reviews.⁽⁴³⁾ In addition, Section 6(b)(8) of the Occupational Safety and Health Act of 1970 states that when federal OSHA promulgates new standards that differ substantially from existing nongovernmental consensus standards, the secretary must explain "why the rule as adopted will better effectuate the purposes of this Act than the national consensus standard."⁽⁴⁴⁾

The issue of third-party participation in site health and safety inspections was a major point of discussion at the July 20–21, 1994, "Revitalizing OSHA" stakeholders meeting. Approximately 90 of the nation's health and safety experts gathered in Washington, D.C., to discuss the future of OSHA.⁽⁴⁵⁾

The third party certification concept was not supported by most in attendance. Labor representatives spoke against the idea due to uncertainties related to conflicts of interest inherent to auditor-company relationship. The corporate sector did not support the idea citing limited resources that would have to be diverted from productive health and safety programs to hire health and safety auditors.

Federal OSHA cited overworked compliance inspectors and lack of financial resources as rationale for the development of a third-party certification model. Labor suggested they might not object to the idea under certain conditions. These included (1) the right to participate in the site health and safety inspections to ensure hazards were listed and scheduled for abatement, and (2) the opportunity to review third-party inspection findings.

ISO OSHMS?

Three weeks after the July 1994 OSHA stakeholders meeting, an ad hoc group of individuals from the U.S. TC-207 Environmental Management Systems Technical Advisory Group met in Washington, D.C., to discuss the issue of developing an ISO 9000/14000 compatible occupational safety and health standard.⁽⁵⁾ Although the minutes of the meeting do not reflect any official position of the attendees, they do shed light on some of the issues germane to the development of an ISO compatible OSHMS.

A summary of the ad hoc committee's findings in support of such a standard included (edited for brevity and clarity):

- Creating a unified standard combining ISO 9000, 14000, and health and safety could simplify implementation and reduce the overall costs of attaining separate registration for each standard independently.
- Such a standard could be companion to OSHA VPP to reduce liability exposure in the United States.
- An OSHMS could improve employee health and safety.

- It could result in a competitive advantage vis-à-vis less sophisticated competitors.
- ISO may be a good forum for consensus building.
- An OSHMS could be a basis for withstanding additional command and control regulations at the domestic level.

The ad hoc committee cited these disadvantages:

- An OSHMS could intrude into the labor-management relationship.
- There would have to be a commitment of additional resources to the development and implementation of yet another standard.
- It could increase liability exposure from regulatory and common law perspectives.
- Labor would play a major role in the development of such a standard.
- Sensitive issues such as process safety, ergonomics, safety committees, and possibly even child labor might be on the table.
- Europe might use ISO as a forum to export their social agenda to create a competitive advantage.

There is some evidence that ISO may begin formal deliberations on the OSHMS issue in the near future. ISO TC-207 passed a formal resolution at their meeting in May 1994 requesting the ISO Technical Management Board to "determine whether there is a need to evaluate the desirability for standardization in the area of occupational health and safety management." A letter containing the resolution was forwarded to the Technical Management Board in August 1994.⁽⁴⁵⁾ Also, the British Standards Institute, regarded as a major force in the development of ISO 14000, published its draft guide to health and safety management systems in December 1994.⁽⁴⁶⁾

General Agreement on Tariffs and Trade (GATT)

Negotiations of the Uruguay Round of GATT concluded with a draft document now in the ratification phase by national governments. The agreement has several sections dealing with international standards and standards-setting processes.⁽⁴⁷⁾

GATT actively encourages countries to participate in the development of international conformity assessment systems and does not preclude development of national standards.⁽⁴⁸⁾ The treaty also includes a mechanism for providing training and special consideration for developing countries.

Role of National Standards in the International Standards Development Process

The importance of national nongovernmental standards should not be overlooked. A number of American third-party standards writing organizations, such as ASTM and Underwriters Laboratories (UL) develop standards through a consensus processes, thus bringing all interested stakeholders into the development procedure. The standards these organizations develop

and publish are U.S. national standards as long as the development procedure complies with ANSI's "Procedures for the Development and Coordination of American National Standards."⁽⁴⁹⁾ As noted earlier, OMB Circular A-119 encourages the development and use of national standards.

Understanding the relationship between national and international standards is important. National standards provide three critical contributions to the international standards process. First, the national standards process provides for consensus among appropriate stakeholders. The international process provides for consensus among countries and assumes that the appropriate stakeholders have already participated in a national process. Second, the national standard assures that important national issues are addressed in the event that the international document is inadequate. This is particularly important for standards with broad scopes such as environmental management. There are more stakeholders for these standards than for more narrowly defined product specification standards. The international process does not ensure broad stakeholder participation. Third, the presence of a national standard and its associated committee of experts provides the method for ready adoption of the international standard if it meets national needs. When the national process is linked with the international process, the system can produce good international standards.

DISCUSSION

Advantages of an OSHMS

Numerous incentives can be cited in support of an ISO OSHMS. Prevention-oriented occupational and environmental health programs should be integrated, not considered as separate entities, with the design phases of industrial processes. As such, an ISO OSHMS would be compatible with the scope of ISO 9001, with the net effect of minimizing the number of internal and external audits to which companies are subjected. By harmonizing ISO 9000, 14000, and a new OSHMS, companies could address the logistical and financial barriers associated with multiple external evaluations.

Multinational corporations may benefit from the evolution of complex intercountry philosophies to a singular health and safety approach. Exchanges of expertise (within the same company) in health and safety, resulting in substantial cross-training, might be encouraged as occupational health professionals would be using similar procedures to resolve similar problems. ISO 9000 does not specify how companies must design quality systems, nor would an OSHMS. Therefore, innovation would be encouraged.

There also could be benefits built into the system that would be favorable to small ISO OSHMS registrants. As noted earlier, several large U.S. firms are already showing a preference toward using suppliers with, or conforming to the principles coupled to ISO 9000 registration. Small ISO registered firms, traditionally outside of OSHA oversight, could be brought into progressive mainline occupational safety and health management.

There also could be other incentives built into the system for attaining registration. Contractual language could require that trade partners be OSHMS registered to be considered for major

business contracts. This also could apply to U.S. federal contract awards. Also, corporate insurance premiums could possibly be reduced by participation in an OSHMS or a VPP designed program.

The language of the GATT agreement supports creation of and participation in development of international conformity assessment standards.⁽⁴⁷⁻⁴⁸⁾ The agreement also suggests that developed countries, when requested, assist developing trade partners in their efforts to comply with technical standards and to give them special consideration with conformance. If the spirit and intent of GATT are applied to an ISO OSHMS, developing countries could be provided time and technical assistance without fear of trade retaliation to develop conformance strategies that are suitable to local social and political conditions. Achievement levels could mirror those of the VPP: Star, Merit, and Demonstration. Finally, GATT as currently drafted would not interfere with American public or private standards-making activities.

The utility of ISO-type occupational health consensus standards could benefit U.S. workers and workers throughout the world. The development of these standards could alleviate some of the inequity inherent in safety and health regulations that differ from country to country. Relevant national specification standards for occupational safety and health could be nested in the program requirements of such an ISO-type standard. The Big Three U.S. auto makers have suppliers located in most of the world. All of their suppliers will comply with the QSR.⁽²⁰⁾ It is the price of conducting business. Worker occupational safety and health should be provided the same consideration.

American labor voiced a strong opinion against third-party auditing at the OSHA stakeholders meeting. However, labor did suggest some conditions that, if designed into a third-party review system, would make the concept less objectionable. These conditions would probably involve employee participation in (1) site health and safety audits, (2) developing prioritized corrective action plans, and (3) publicizing audit findings. Many of these functions already occur under OSHA's VPP.

Many public health professionals may take for granted the significant contributions third-party certification already has made toward the protection of public safety, public health, and the environment during the last century. The reliance on third-party certification has been important as an adjunct to regulatory oversight in all developed countries including the United States.

The best known example in the United States is certification of products for electrical and fire safety by Underwriters Laboratories. The presence of the UL mark provides assurance to consumers that products bearing it conform to a rigorous set of standards for product safety, and that there is a process to assure continuing conformance. In the same manner NSF International has been providing third-party certification for products and services impacting public health and the environment in the United States over the last 50 years. The public sector has developed such confidence in NSF International, its standards and certification programs, that in 1987 the U.S. Environmental Protection Agency canceled its own advisory program for drinking water additives in favor of NSF International's third-party program.⁽⁵⁰⁾

The important attributes of credible third-party programs are (1) a credible standard or regulation against which to evaluate a

product or service, (2) audits (often unannounced), (3) periodic review, and (4) conformance of the certifier to a rigid set of rules. In the United States the standard for certifiers is ANSI Z34.1, Third Party Certification Programs for Products and Services. Third-party certifiers are "accredited" to this standard.

An ISO OSHMS model of independent third-party inspectors potentially could provide a value-added service to federal OSHA and its state partners. First, the registration process would not interfere with OSHA enforcement activities. Second, firms that receive ISO OSHMS registration potentially could be removed from OSHA's programmed inspection schedule thus reducing some of the work load from their compliance personnel. As a consequence, OSHA could focus its limited resources on the most immediate health threats to American workers. This would minimize bureaucracy while maximizing worker health and safety.

Employees could feel reassured, as registrars return to registered sites at least annually in both announced and unannounced inspections. These audits theoretically ensure that ongoing improvements in performance are being achieved. The ISO registration approach is very similar to the methodology employed by VPP, whose member companies enjoy illness and injury rates far below industry averages.

Disadvantages of an OSHMS

While the incentives to develop an OSHMS are numerous, so are the disincentives. The standard development process, driven through a consensus approach, requires that all stakeholders be afforded the opportunity to participate. Reaching consensus on potentially polarizing philosophies to occupational safety and health may be complicated and time consuming at both national and international levels.

The ISO "one country one vote" model is a second potential confounder. European countries, with their numerical superiority, may dominate discussions. Domestic concerns also will be numerous. ANSI is the sole voting American representative to ISO. Its single vote represents all U.S. interests. Ultimately, one of the major interest groups, either business or labor or both, may be displeased with the outcome of the proceedings.

The potential for fraud and abuse through unethical registrar conduct is a serious problem. Receiving ISO registration is by and large only as good as the accredited registrar that approves ISO 9000 status for a particular site. In the United States, RAB, under the umbrella of ANSI, assures competence of U.S. third-party registrars. The Europeans, however, prefer government-related recognition systems. In response the U.S. National Institute of Standards and Technology (NIST) has proposed developing a National Voluntary Conformity Assessment System Evaluation (NVCASE) program.⁽⁸⁾ Through this program the U.S. government will assure other governments that U.S. assessment bodies are competent to provide results for regulatory purposes. However, the NVCASE program is likely to be very limited in scope and function.

The U.S. Independent Association of Accredited Registrars was formed in 1993. This nongovernmental group is attempting to ensure integrity and consistency of the registration process while addressing the inevitable conflict of interest issues.

It is important that when third-party certification programs are established, policies and procedures governing the program are developed with input from all parties at interest. The frequency of audits, makeup of the audit teams, and important issues of interpretation of standards and regulations can be established to the satisfaction of the stakeholders. Stakeholders, such as federal and state OSHA, unions, and interested association members (e.g., VPPPA, Chemical Manufacturers Association, etc.) could provide oversight of the third-party programs to increase user confidence as necessary.

An ISO OSHMS also may be redundant and expensive for corporations or associations already engaged in their own productive employee-driven health and safety programs. An example of such a program is Chemical Manufacturer's Responsible Care Employee Health and Safety Code.⁽⁵¹⁻⁵²⁾ These successful programs would likely incur direct and indirect costs in the process of reconfiguring their existing program into ISO format. Employees and management alike also likely would have to learn ISO "language." A standard, similar in scope to the ISO 8402, probably would have to be developed for an OSHMS.

Other Considerations

The inevitability of an ISO occupational safety and health standard is unclear. Some see British development of their own safety standard as an indicator that they may be positioning themselves to produce an archetype from which further refinement toward an ISO standard could be rationalized. This notion is based on the fact that the British were important players in forwarding the 14000 series standards currently under development and have also developed a risk assessment model for occupational and environmental exposures.⁽⁵³⁾ In addition, a recent report funded by European Union suggests certifying occupational hygiene activities under an ISO 9000 or similar model.⁽⁵⁴⁾

American labor, business, and government should consider collaborating, under the guidance of ANSI, on the development of a U.S. national standard for occupational safety and health management and performance evaluations. Why? First, OMB Circular A-119 supports development of national standards. Second, if the Europeans or Canadians provide leadership in this area by developing their national standards first, America may spend considerable time playing catch-up at the international level. If we as a nation begin consensus deliberations on our national vision of occupational safety and health management and performance standards, we may develop a technical document that could be used as the template for international consideration.

A theoretical national standard might look to models such as OSHA's VPP, which is employee driven and contains nested OSHA standards, as the starting point for discussions. The program has shown that it can be applied in divergent industries, is generalizable, performance based, and has successfully, albeit in small numbers, used third-party inspectors.

The concept of developing an ISO OSHMS likely will receive review by the ISO Technical Board based on the May 1994 TC-207 resolution. These actions should not be interpreted to imply that some decision on the issue is imminent. Months or

years may pass before the ISO board makes a determination whether or not to develop applicable standards.

How might an ISO OSHMS be developed and what might it contain? The environmental management standards now under development might provide a good analogy to answer this question.⁽²¹⁾ If ISO decides to develop an OSHMS, it would likely convene a committee similar to TC-207, which is managing the development of the 14000 series environmental standards. A technical committee secretariat (committee chairperson) would be selected and subcommittee assignments (including subcommittee secretariat) would be given to member nations. Possible OSHMS subcommittees might reflect major technical areas and might include occupational management systems, occupational health auditing procedures, occupational health performance evaluations, and maybe terms and definitions. The United States likely would develop a technical advisory group (TAG) whose members would sit on each of the various sub-committees to ensure U.S. interests were being adequately represented.

The ISO OSHMS likely would develop over the process of years as various subcommittees completed their work. As the international subcommittees completed drafts of their respective standards, the subcommittee secretariat and technical committee secretariat would make resolutions that the draft standard be raised to draft international standard status. If the resolution passed at the technical committee level (recall that each country gets a single vote), then the standard would be sent to a technical officer at ISO in Geneva. The standard would then be published in French, Russian, and English.

If an ISO OSHMS were developed, who would do the registration audits in the United States? There are 24 RAB-accredited registrars (in addition to those accredited by the RvC and possibly others) in the United States. These institutions could collaborate with board-certified personnel to conduct occupational hygiene and safety site inspections. By way of illustration, the American Industrial Hygiene Association, in collaboration with the American Society of Safety Engineers, might work with an accredited registrar such as public health experts NSF International. The interdisciplinary approach of allied health and safety professionals could compliment NSF International's fundamental knowledge of public health and mastery of the ISO registration process.

Federal OSHA could play a critical role in the transition and management phases. Agency experts could assist in the role-delineation process of the key players noted above. Additionally, OSHA could participate in site verifications as participants or observers and possibly could provide some degree of database management.

Under an OSHMS model the issue of auditor qualifications also would have to be addressed. One possible approach is to use registrars accredited by RAB, who would in turn retain audit teams comprised of board-certified industrial hygienists (CIHs) and certified safety professionals (CSPs). ISO Standard 10,011-2 also suggests one method of evaluating auditor technical competence is through possession of a nationally recognized board certification. CIHs and CSPs satisfy those criteria. The RAB also could implement a training program for OSHMS auditors. Federal OSHA's VPP SGE requirements also possibly could provide

a template in the development of an appropriate auditor qualification model.

Reasonable individuals could conclude that board-certified industrial hygiene and safety consultants would probably benefit greatly from the development of an ISO OSHMS. Given the enormous potential, guidelines would have to be developed to remove the incompetent or those auditors found guilty of management collusion or fraud. The American Board of Industrial Hygiene code of ethics, linked with the existing RAB guidance, might be useful in the evaluation of such cases.

The issue of auditor/registrar indemnification from lawsuits following accidents, injuries, or citations subsequent to company OSHMS registration also would have to be considered. ISO 9000 is not a product specification standard. The voluntary American EMS standard, NSF 110, audits against company goals. These goals may or may not include applicable government standards.⁽⁵⁵⁾ An ISO compatible OSHMS, to be effective, should have applicable federal and state standards imbedded.

Perhaps the greatest challenge will be in the development phase of the auditing tool and site evaluation procedures. The auditing tool should be generalizable, as are the 9000 standards and VPP model, with risk characterization based on projected severity and probability outcomes. A quantitative auditing tool likely would be justified so improvements in occupational safety and health performance could be tracked over time. Similar tools currently are used in general industry and consulting.⁽⁵⁶⁻⁵⁷⁾ An assessment instrument could be constructed that is parallel to that found in an ISO auditing tool.⁽⁵⁸⁾

For an ISO OSHMS to be acceptable to western hemisphere rank and file workers, considerable participation in the entire auditing process would be both requested and appropriate. Employee representatives likely would want to accompany site auditors or have responsibilities during the site investigation. Employees should be interviewed during the process and audit findings should be made public. Employees also should have an integral role in the prioritization of corrective actions. This approach has been found successful in the U.S. VPP programs.

CONCLUSIONS

A potential link between the VPP concept of employee-driven health and safety programs, the fiscal limitations of the U.S. federal budget, and the underlying need to improve workplace health globally is found in the ISO 9000 model. Based on emerging professional and national interests as well as the value-added features of such a model, the potential advantages and disadvantages of developing an ISO 9000 compatible OSHMS merit further discussion and debate.

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