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Development of an ISO 9000-Compatible Occupational Health Standard—II: Defining the Potential Benefits and Open Issues

The International Organization for Standardization (ISO) is currently voting on a final draft of ISO 14000 Environmental Standards that follow the general philosophy of ISO 9000 product quality standards. Should the international community also consider development of an ISO 9000-14000 compatible occupational safety and health management standard (OS&HMS) or an environment, safety, and health management standard? The first paper in this series (*Am. Ind. Hyg. Assoc. J.* 56:599-609 [1995]) introduced this subject, reviewed the historical precedents, and identified the underlying issues. In this paper the authors identify some of the potential benefits and most critical open issues that may affect the viability of an OS&HMS at the national and international levels. Twelve potential benefits are identified in the major categories of national and international, and industrial and governmental benefits; 16 open issues are identified in the major categories of applications, ethics, cost, and international issues.

Keywords: International Organization for Standardization, occupational safety and health management standard

The approach of third-party registration of federal environment, safety, and health (ES&H) and occupational safety and health (OS&H) systems⁽¹⁾ represents the potential for one of the most significant paradigm shifts since the creation of the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA). Independent third-party verification of environmental programs is currently being considered by the U.S. EPA under its Environmental Leadership Program.⁽²⁾ Indeed, in a recent Interim Policy Statement, EPA said: "EPA . . . recognizes the development of and growing reliance on international voluntary management standards [MS] in the U.S. and other countries. These standards, *if properly crafted and implemented*, can provide a powerful tool for organizations to improve . . . compliance with environmental requirements and move beyond compliance through innovative approaches to pollution prevention."⁽³⁾

Third-party verification of occupational hygiene program adequacy has been promoted as a possible mechanism to assist OSHA in achieving its mission.⁽⁴⁾ In actuality, third-party participa-

tion in voluntary federal health and safety site approval audits has already occurred.⁽⁵⁻¹¹⁾

The scope of voluntary private sector inspection activities in the OS&H arena currently appears limited to programs such as OSHA's and the Department of Energy's Voluntary Protection Programs (VPP). However, the larger question may be asked: Could nongovernmental ES&H professionals effectively replace OSHA and EPA personnel in the routine performance evaluations of industrial ES&H programs? Joseph Dear, assistant secretary for OSHA, addressed this issue during the 1994 keynote address to the American Industrial Hygiene Conference.⁽¹²⁾

A strategy that employs third-party registrars, based on an international ISO 9000-harmonized occupational safety and health management standard (OS&HMS) or environment, safety, and health management standard (ES&HMS), might represent a paradigm shift from a command-and-control approach to safety and health to a voluntary approach that is international in scope. This strategy would focus on management systems to supplement, complement, and in some cases obviate the need for reliance on prescriptive

regulation of specified technical requirements. This solution is based on a strategy, tactics, and instruments that are harmonized with those of the ISO 9000 (manufacturing systems quality) and 14000 (environmental management systems) standards.^(1,13-24)

There have been many recent publications and position statements both for and against the development of an ISO 9000-compatible OS&HMS or an ES&HMS.^(25,26) Both positions are useful in advancing the evaluation of this new approach. The position against is summarized below:⁽²⁶⁾

- (1) OS&H is a highly regulated field, so such a standard would play no useful role.
- (2) Since it would play no useful role, it is a waste of resources.
- (3) Since it is a waste of resources, no drafts of such a standard should be developed.
- (4) Since no drafts should be developed, there will be no need to harmonize such an OS&H management standard with ISO 14000.
- (5) Even a workshop to discuss this approach is a superfluous exercise.
- (6) Working to evaluate open issues would infer support of such a standard.
- (7) A firm stand on this issue will help people to understand that such a standard is not inevitable.

There are undoubtedly genuine concerns underlying the above position. However, a systematic evaluation of the issues reveals that there are highly significant potential benefits and open issues that have not been evaluated.

These potential benefits and open issues must be subjected to rigorous, quantitative policy analysis.^(27,28) Some of the issues have been discussed by Dyjack and Levine.⁽¹⁾ However, the following is an updated, more complete listing and discussion of each issue (arranged by major subject area).

POTENTIAL BENEFITS

The potential benefits of a functioning, ISO-harmonized, ES&H or OS&H management system standard would likely include the following.

National/International Benefits

The utility of ISO-type ES&H consensus standards could benefit the U.S. environment and workers and the environment and workers throughout the world. The development of these standards could alleviate some of the inequity inherent in ES&H regulations and governmental compliance activities that differ from country to country. Relevant national specification standards for ES&H would be nested in the program requirements of such an ISO-type standard. Conformance to the ISO standard requires compliance with relevant national and local standards.

The ISO process is well-developed and has within it the 9000 and 10000 series protocols for standardized auditing, auditors, and registration procedures.

Prevention-oriented ES&H programs should be integrated, not considered as separate entities, with the design phases of industrial processes. As such, an ISO ES&HMS 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 the ISO 9000 and an ES&H 14000, 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 single health and safety ap-

proach. Exchanges of expertise (within the same company) in ES&H, resulting in substantial cross-training, might be encouraged as ES&H professionals would be using similar procedures to resolve similar problems. ISO 9000 does not specify how companies must design quality systems, nor would an ES&HMS. Therefore, innovation would be encouraged.

There could also be other incentives built into the system for attaining registration. Contractual language could require that trade partners be ES&HMS registered to be considered for major business contracts. This could also apply to U.S. federal contract awards. Also, corporate insurance premiums could possibly be reduced by participation in an ES&HMS.

The language of the General Agreement on Tariffs and Trade (GATT) supports creation of and participation in development of international conformity assessment standards.⁽²⁹⁻³¹⁾ The agreement also suggests that developed countries, when requested, assist developing (less developed countries, or LDCs) trade partners in their efforts to comply with technical standards and give them special consideration with conformance.

If the spirit and intent of GATT are applied to an ISO ES&HMS, LDCs could be provided time and technical assistance, without fear of trade retaliation, to develop conformance strategies suitable to local social and political conditions.

Finally, GATT as currently drafted would not interfere with American public or private standards-making activities.

Industry and Governmental Benefits

By promoting the use of industry-driven ES&H management systems, this policy reaffirms the belief that industry is the main engine of sustained economic growth that should be unfettered by specification standards. Third-party registration is a market-based strategy for compliance, which thereby creates flexibility and incentives for innovation.

There could also be benefits built into the system that would be favorable to small ISO ES&HMS registrants. 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 EPA and OSHA oversight, could be brought into progressive mainline ES&H management.

An ISO OS&HMS model of independent third-party inspectors could potentially provide a value-added service to federal EPA, OSHA, and its state partners. First, the registration process would not interfere with EPA or OSHA enforcement activities. Second, firms receiving ISO ES&HMS registration could potentially be removed from EPA's and OSHA's programmed inspection schedule, thus reducing some of the work load from their compliance personnel. As a consequence, EPA and OSHA could focus their limited resources on the most immediate health threats to American workers and the environment.

This is a policy reform that fits into the category of the application of existing knowledge in pioneering attempts to effect institutional change to promote innovation.

This is a shift in protection strategies from the pollutant-by-pollutant, end-of-pipe, command-and-control approach to a prevention system-oriented approach. Provisions would be incorporated into new and existing regulations and programs that maximize flexibility for industry.

Many environmental and public health professionals may take for granted the significant contributions third-party certification have already 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. In this paradigm, third party accredited registrars and certified auditors would become part of an important national and international business activity.

OPEN ISSUES

The potential benefits of this approach must be evaluated in light of the open issues⁽³²⁾ and strategies designed to overcome those issues. The open issues that have been identified to date are summarized below.

Application Issues

It is important that when third-party certification programs are established, policies and procedures governing the program are developed with input from all interested parties. The frequency of audits, makeup of the audit teams, and important issues of interpretation of standards and regulations will have to be established to the satisfaction of the stakeholders. Stakeholders, such as federal and state EPA and OSHA, environmental groups, unions, and interested association members (e.g., Voluntary Protection Programs Participants Association, Chemical Manufacturers Association, etc.) could provide oversight of the third-party programs to increase user confidence. The mechanism for this has not been established.

The ISO registrars auditing government-regulated companies must understand the special characteristics and good management practices requirements of those companies, and of the industry sectors being audited.

The liability of the registrar must be addressed. A registrar who audits and registers an entity for ES&H purposes might be sued for errors and omissions if there is an ES&H-related unplanned occurrence at a later date. What if an explosion occurs after registration is granted? Will the auditor and the registrar be liable for damages?

On the other hand, can the auditor and the registrar be sued by the company seeking registration if registration is not granted? It may be more difficult to address these issues in the ES&H arena than it is in the production system quality (ISO 9000) arena. Should a government entity be required to "hold harmless" or otherwise indemnify auditors and registrars?

The relationship between the required level of process documentation and the detail at which conformity assessment occurs must be evaluated so that the quality system does not promote mediocrity. To what extent will such a system require continuous improvements as opposed to undocumented mediocrity? Little objective data is available to evaluate the effectiveness of ISO 9000 registered suppliers, and none for ISO 14000 registration (since the ISO 14000 system is not yet in place). For example, it is unclear whether ISO 9000-registered suppliers provide quality products or services more consistently than their nonregistered competitors.

The relationship between governmental regulatory agencies and nongovernmental authorities that accredit quality systems registrars must be explored.

Provisions must be available to provide for the evaluation and updating of ISO quality system standards based on experience, feedback, or changes in regulatory requirements.

Governmental regulatory agencies must have at least indirect enforcement authority when firms claim compliance with or give guarantees of compliance with an ISO ES&HMS or OS&HMS. OSHA and EPA cannot completely cede their authority to ISO

third-party registrars. The balance between governmental enforcement and ISO registration must be found.

Ethical Issues

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 who approves ISO 9000 status for a particular site. In the United States, the Registrar Accreditation Board (RAB), under the umbrella of the American National Standards Institute (ANSI), assures competence of U.S. third-party registrars. The Europeans, however, prefer government-related recognition systems.

This has special importance in light of the fact that there are multinational companies that market their services to consult with business entities to (1) aid them in various registration processes, (2) conduct registration audits, and (3) use copyrighted safety rating manuals. This is but one example where a perfectly open process in the hands of an honest, competent consulting company might be misused if a governing system is not in place.

The administration of a conformity assessment registration system would have to protect itself against political, socioeconomic, and public pressure. This pressure could be applied to registrars, auditors, and even to national registrar accreditation entities.

Pressure could come from those seeking to make registration more or less difficult, or from those seeking to use this process as a hidden barrier to trade.⁽³¹⁾ For example, a government procurement process that requires registration against a national or an international standard that is unfairly applied to foreign bidders, might have little to do with improvement of ES&H systems, but rather be directed at keeping foreign entities out of the bidding process for contracts.

Cost Issues

An ISO ES&HMS may also 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 Program.⁽³³⁾ These successful programs would likely incur direct and indirect costs in the process of reconfiguring their existing program into ISO format.

The financial impact of an ISO ES&HMS or OS&HMS must be evaluated for industry (especially small firms or firms that produce low-risk products). This is a critical issue, since primary targets for improvement of ES&H practices are small and medium-sized businesses.

International Issues

The standard development process, driven by a consensus approach, requires that all stakeholders be afforded the opportunity to participate. Reaching consensus on potentially polarizing philosophies to ES&H 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.^(34,35) This is not necessarily a negative or a positive factor. However, ANSI is the sole voting American representative to ISO. Their single vote represents all of U.S. interests. Ultimately, one of the major American interest groups, either business or labor or both, may be displeased with the outcome of the proceedings. This may also be an issue with other countries.

Can ISO standard conformance serve as a trade barrier to external countries? This is the critical GATT legality question.

TABLE I. Potential Benefits and Open Issues of an Environment, Safety, and Health Management Standard

Potential Benefits

National/International

Benefit to environment and workers
Based on ISO 9000 series standards
Integratable with ISO 9000 and 14000
Benefit to multinational entities
International "reach" through procurement language
Probably GATT legal

Industrial/Governmental

Flexibility and incentives for innovation
Helps small/medium entities into ES&H management systems
Leverage of scarce resources for governmental agencies
Existing knowledge to effect institutional change
Prevention system approach
Opportunities for ES&H professionals

Open Issues

Applications

Need for policies and procedures
Industry sector-specific practices
Liability of the registrar
Ensuring against a drift to mediocre performance
Relationship between government and registrars
Evaluation and updating of ISO system requirements
Governmental enforcement authority

Ethics

Potential for fraud and abuse by registrars
Political, socioeconomic, and public pressures

Costs

Added expense for companies with responsible programs
Financial impact on small and medium entities

International

Difficulty in reaching consensus
One vote for each country in the ISO process
Potential as a trade barrier and GATT illegal practices
Alternate use of trading blocs and unilateralism
Internationally recognized worker rights

There have been GATT challenges to national legislation and regulations.^(29,31) These challenges include the Mexican Tuna-Dolphin Case (September 1991), and the challenge to the U.S. Corporate Average Fuel Economy (CAFE) Gas Guzzler Tax (1994). The issue of GATT-legality of procurement or taxation regulations based on international standards for ES&H is not entirely clear. (A study of this specific issue is in progress.)

The idea must be explored that aggressive unilateral action might be more effective on the part of the United States (and of other countries with advanced ES&H systems in place) than depending on a multilateral, GATT-legal approach to national and international ES&H problems.^(29,31)

The question must be explored of how multilateral or unilateral approaches are used within the context of trading blocs (such as the North American Free Trade Agreement, the European Union, or other such trading blocs).^(29,31)

The question of the linkage of the issue of occupational safety and health with the social clause of U.S. trade and labor standards

and internationally recognized worker rights must be addressed. Collective bargaining, forced labor, minimum age, and wages and hours, while of primary importance, may be confused with or used to impede occupational safety and health.⁽³⁶⁾

CONCLUSIONS

A significant paradigm shift has been proposed. There are many potential benefits to such a shift. These benefits may accrue to public health, the ES&H profession, worker protection, governmental regulatory efforts, and to business entities. However, there are important open issues that must also be evaluated (Table I).

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