

Management System Standards' Growing Role In Compliance

Law360, New York (January 28, 2016, 4:21 PM ET) --

Compliance programs aimed at preventing and detecting noncompliance are an essential component of most companies' risk management programs. If noncompliance does occur, the effectiveness of compliance programs will typically be taken into account by the government in determining the nature and extent of any enforcement that may be taken.[1]



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At the same time, voluntary consensus standards have become part of the legal landscape. Though developed in a nonregulatory multistakeholder context, standards are used by governmental authorities around the world. In the U.S., the National Technology Transfer Act of 1995 directs federal agencies to use applicable standards in regulations (or demonstrate why the relevant standard should not be used).[2] A database that tracks standards that have been incorporated by reference into federal regulations has over 15,000 entries.[3]

Beginning in the late 1980s, standards development bodies began expanding into "management systems" standards aimed at high-visibility topics, including product quality, environmental protection, cybersecurity and bribery. These standards have attracted the interest of the compliance program community as well as governmental authorities. This trend began with the publication of the International Organization for Standardization's ("ISO") ISO 9001 quality management systems standard in 1987. Implementing ISO 9001 has blossomed into a condition of doing business in many economic sectors, with over 1.1 million "certificates" having been issued by accredited third-party auditors to organizations that have implemented ISO 9001.[4]

The publication of the ISO 14001 environmental management system ("EMS") standard in 1996, for which approximately 325,000 certificates have been issued, brought management systems standards directly into the compliance program world. ISO 14001 is also woven into the fabric of environmental compliance programs in the U.S. [5] ISO 14001 has been recognized by the U.S. Environmental Protection Agency as a framework for an effective environmental compliance program, and the EPA is implementing ISO 14001-based EMS at its own facilities.[6] Many major federal agencies have or are implementing EMS based on ISO 14001,[7] and it is widely used as a starting point for EMS in the private sector, even by facilities not seeking third-party certification.[8] Requirements to implement ISO 14001-based EMS have frequently been incorporated in consent decrees resolving enforcement cases.[9]

Recent developments in management systems standards will continue the convergence with compliance programs. First, in 2015, ISO 14001 was significantly revised for the first time since its initial publication

in 1996 (there was a minor revision in 2004). The revised ISO 14001 more closely aligns the standard with ISO 9001, and increases the emphasis on top management leadership, strategic forward-looking risk management and environmental protection, transparency and communication, and life-cycle thinking. The revised ISO 14001 has elements that go “beyond compliance,” a feature typical of ISO management system standards.

Second, the ISO is in the final stages of drafting ISO 37001, an anti-bribery management systems standard.[10] Evaluating, designing and implementing anti-bribery programs aimed at compliance with laws such as the Foreign Corrupt Practices Act and the United Kingdom’s Bribery Act has become a thriving cottage industry. The government has developed guidance on what constitutes an effective anti-bribery program.[11] The effectiveness of such programs are regularly taken into account by enforcers when investigating alleged noncompliance,[12] and requirements to create or enhance compliance programs are a regular feature of agreements settling enforcement cases.[13]

The impetus for ISO 37001 came from a standard developed by the British Standards Institute aimed at providing direction on what constitutes having adequate anti-bribery procedures in place, which is a defense under the Bribery Act to a charge of failing to prevent bribery.[14] The work on ISO 37001 began in 2013, and it is expected to be published in late 2016. Over 40 countries (including the U.S.) are participating in the drafting of ISO 37001, including representatives from government, academia, industry, consulting firms and nongovernmental organizations. These are not government-to-government negotiations; the participants negotiate as peers under the umbrella of national standards bodies.

ISO 37001 is characterized by the same structure of ISO 9001 and 14001. Organizations will be expected to commit to comply with applicable anti-bribery laws, identify their bribery risks and legal requirements, and implement procedures to manage those risks and comply with the law (including training, auditing, contract/vendor management, etc.). Organizations implementing ISO 37001 will be able to seek third-party certification to the standard if they so desire.

It will be interesting to see how these new developments play out in the marketplace and public policy. The increased complexity and demands of the new ISO 14001 may discourage some organizations from taking it up, but it may make it more attractive to governmental authorities and other stakeholders. The big question regarding ISO 37001 is whether it will follow in the footsteps of ISO 9001 and 14001 and become a prominent feature in commercial relationships and whether it will be viewed by the authorities as a credible foundation for an effective anti-bribery compliance program.

Organizations seeking to implement or enhance their anti-bribery compliance programs might find ISO 37001 useful because it will create a common framework and vocabulary that may be more readily understood within the organization and throughout the value chain (particularly since the standard has a similar “look” as the widely implemented ISO 9001 and 14001 standards). Using the existing global infrastructure for third-party certifications may be attractive as an efficient method of driving implementation of compliance systems throughout the value chain and as an element of vendor due diligence.

Third-party certification to systems standards such as ISO 9001, 14001 and 37001 goes to the design and implementation of the system and is not a certification of performance; i.e., the fact that a company is “ISO 14001 certified” is not a 100 percent guarantee of regulatory compliance, nor will certification to ISO 37001 mean that no bribery has or will occur. However, this should not come as a surprise: Implementation of any system is never a guarantee of perfect performance. Rather, whether it is the

sentencing guidelines, the U.S. Department of Justice's prosecutorial guidelines, or the ISO standards, the expectation is that organizations that implement such systems are more likely to successfully identify and comply with applicable legal requirements.[15]

It remains to be seen the extent to which the DOJ and the U.S. Securities and Exchange Commission, and enforcement authorities in other countries, will be willing to take anti-bribery management systems based on ISO 37001 into account in their regulatory and enforcement policies in the same way that, for example, ISO 14001 is viewed as a credible framework for environmental compliance systems. It is already well established that organizations can get "credit" for implementing effective anti-bribery compliance systems; the unknown is whether systems based on ISO 37001 will do the trick.

Just as there was a certain amount of institutional resistance to ISO 14001 when it was first published, one might expect that ISO 37001 will receive a cautious reception from enforcers. The source of ISO standards can sometimes be a stumbling block, since they are developed in a nonregulatory, multistakeholder international context where the government's hands are not on the controls. Further, the rather nonlegalistic style and structure of the standard can be off-putting for authorities used to a "command and control" style. However, these factors should not be barriers to evaluating ISO 37001 on its merits. Indeed, many provisions of ISO 37001 were either revised or added based upon input from those with significant experience implementing FCPA compliance systems.

In addition, enforcers and policymakers should take into account the benefits of having a common international framework and vocabulary for anti-bribery compliance. For example, given the global nature of the medical device industry, the U.S. Food and Drug Administration has found value in working to make its regulations for the manufacture of medical devices consistent with the relevant ISO standards.[16] Given the concerns about the potential nontariff trade barrier consequences of anti-bribery requirements, the possible applicability of the presumption of legality attached to policies based on international consensus standards under the "technical barriers to trade" provisions of the World Trade Organization should not be ignored.[17]

Regardless of how the revised ISO 14001 or ISO 37001 are implemented by the private sector or received by government authorities, it is clear that there is a convergence between the compliance programs and the growing family of ISO management system standards designed to help companies identify and manage a range of risks. This presents stakeholders with advocacy opportunities in both the development of the standards themselves and with respect to how those standards will be used in the private and public sectors. It also suggests that it might be prudent for organizations that implement compliance programs to at least monitor, if not participate in, the development of management system standards that could become models accepted by government authorities.

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[1] See, e.g., §8B2.1 of the U.S. Sentencing Commission's Sentencing Guidelines Manual, which describes the elements of an ethics and compliance program; Principles of Federal Prosecution of Business Organizations, Section 9-28.000 of the U.S. Attorney's Manual.

[2] Pub. L. 104-133, 110 Stat. 775 (1996). The Office of Management and Budget is in the process of revising OMB Circular A-119, which describes how agencies are to implement the NTTA. 79 Fed. Reg. 8207 (Feb. 11, 2014).

[3] https://standards.gov/sibr/query/index.cfm?fuseaction=rsibr.total_regulatory_sibr, last viewed on January 4, 2016. Creating legal requirements through the incorporation by reference of standards has been a controversial issue. See, e.g., 79 Fed. Reg. 66267 (Nov. 7, 2014); Gluck, O'Connell and Po, Unorthodox Lawmaking, Unorthodox Rulemaking, 115 Col. L. Rev. 1786 (2015); Bremer, Incorporation by Reference in an Open-Government Age, 36 Harv. J.L. & Pub. Pol. 131 (2013).

[4] See, http://www.iso.org/iso/iso_survey_executive-summary.pdf, last visited on January 11, 2016.

[5] For a more detailed discussion of EMS and environmental law, see Bell, C., Environmental Management Systems and Environmental Law in Environmental Law Handbook, 22d Ed. (2013).

[6] See, <https://www.epa.gov/ems>, last viewed on January 11, 2016.

[7] See, <https://www.fedcenter.gov/programs/EMS>, last viewed on January 11, 2016.

[8] For example, the American Chemistry Council has, through RC 14001, integrated ISO 14001 into Responsible Care®.

[9] See, e.g., U.S. v. Massachusetts Bay Transportation Authority, C.A. No. 04CV10481-MEL (D. Ma), 69 Fed. Reg. 15381 (Mar. 25, 2004); U.S. v. Koppers Industries, Inc. (N.D. Alabama, Dec. 13, 2002); U.S. v. Nucor (D. S.C. Dec. 19, 2000).

[10] ISO in 2014 also published a guidance document on compliance systems: ISO 19600:2014 – Compliance Management Systems -- Guidelines.

[11] See, A Resource Guide to the U.S. Foreign Corrupt Practices Act at pp. 56 – 68 (U.S. DOJ and SEC, 2015).

[12] See, e.g., U.S. v. Peterson, Cr. No. 12—224 (E.D. N.Y. 2012).

[13] See, e.g., U.S. v. Panalpina World Transport, (S.D. Tex., Nov. 4, 2010); SEC v. Veraz Networks, Inc., CV-10-2849 (PVT) (N.D. Cal., June 29, 2010); SEC v. Halliburton Co. and KBR, Inc., 4:09-CV-399 (S.D. Tex, Feb. 11, 2009).

[14] BS 10500 (2011): Specification for an anti-bribery management system (ABMS)

[15] Federal agencies have signaled a willingness to rely on third-party certifications to ISO standards for compliance purposes. For example, U.S. EPA has proposed a rule setting standards for mercury in dental waste water where compliance may be achieved using technology certified as complying with an ISO standard (79 Fed. Reg. 63258 (Oct. 22, 2014)), and also suggested that ISO standards on measuring and

greenhouse gas emissions might be used in plans implementing its recently promulgated Clean Power Plan. 80 Fed. Reg. 64966 (Oct. 23, 2015).

[16] See, e.g., Guidance for Industry, Third Parties and Food and Drug Administration Staff - Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program (FDA, March 19, 2012).

[17] See, e.g., 2013 Report on Technical Barriers to Trade, U.S. Trade Representative (April, 2013). An open issue is whether ISO management systems standards such as ISO 14001 or ISO 37001 would be considered a “technical” standard under the TBT provisions.

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