

**ISO 14001: A Case Study in Certification
at Bayer Pharmaceuticals in Berkeley, California**

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Abstract

The ISO 14001 standard is a voluntary international standard outlining the framework for the creation and implementation of an environmental management system (EMS). Being certified as an ISO 14001 company is considered highly prestigious and valuable but few American companies have chosen to build an EMS and gain certification, possibly due to concerns that ISO 14001 tends to only create a “paper EMS” that does not add environmental value to the company. The Bayer Pharmaceuticals site in Berkeley, California is the only Bayer site in North America currently certified. This study employs a case study methodology to conduct an analysis of the company's certification process in order to lead to an understanding of the factors that prevented the Bayer process from resulting in a valueless ISO 14001 certification. Evidence suggests that the two most important factors in determining whether the ISO 14001 EMS improves the environmental performance of an organization are (1) auditor bias/knowledge of environmental policy and science; and (2) motivating factors within the company for achieving certification.

Introduction

The current environmental regulatory regime is highly command-and-control oriented, with strict sets of rules dictating limits on emissions and often stricter agencies charged with monitoring compliance with the standards. The inherent inflexibility of this system has created adversarial relationships between business and government, and hinders attempts at collaboration (Lally 1998). Growing concern over this state has led to increasing numbers of proposals for cooperation between the two players. Recent proposals in the US and Europe have suggested a more "voluntary" approach to environmental protection in which a general framework would be established and each industry or business could organize their operations and services in the most effective way to work within the parameters of that framework (Andrews 1998). A growing consensus is developing among world-wide industry that environmental protection and compliance are best achieved when environmental factors are integrated into industrial operations in a systematic way (Diamond 1999). Happily, a voluntary framework with both binding but adjustable parameters and a systematic integration of environmental tasks has developed in the ISO 14001 international standard.

The ISO 14000 standards were released in 1996 by the International Organization for Standardization, having been requested by the United Nations following the Rio Environmental Summit (Lally 1998). ISO 14001 is the specific standard that provides guidance for the development of a comprehensive environmental management system (EMS). The EMS is based on the Total Quality Management (TQM) business concept of continuous improvement, or the Plan-Do-Check-Act cycle in which a procedure is developed, implemented, and then reviewed and improved upon if necessary. This cyclic nature ensures that the EMS is both proactive and continuously improving.

While ISO standards are voluntary, market forces have mandated compliance with 14001's predecessor, the ISO 9000 standard for quality management, as a virtual passport to the conducting of international business (Diamond 1999). The expectation is that eventually 14001 will follow suit, and companies without certification will not be able to engage in international trade. This has contributed to the large numbers of European and Asian companies certifying their EMSs under the standard. However, in the US, companies have been both slow to adopt the standard and highly critical of its potential value. Procter and

Gamble, for one, has stated that it specifically did not want to be associated “with the ISO 14001 bureaucracy” (Business and the Environment 1997).

Most criticisms of the standard stem from the perception that certification is essentially an exercise in creating large amounts of paperwork (Buchholz 1999, Business and the Environment 1997). Policy analysts have noted that:

“ISO 14001-certification mandates by large corporations may promote ‘paper EMSs’ in which certification is nothing more than a bureaucratic exercise that does not result in improvements in environmental performance. . . A race to become ISO 14001 certified solely for the sake of certification would erode its value as a tool for better environmental management” (Morrison *et al.* 2000).

This criticism is important because the few case studies on ISO 14001-certified firms that have been performed have noted at least some improvements in environmental performance. These studies have all documented positive impacts of ISO 14001 and have failed to uncover any negative results from undergoing the certification process (Boudouropoulos and Arvanitoyannis 1999, Gunningham and Sinclair 1999, Ruddell and Stevens 1998, Mohammed 2000). But despite this, the perception that certification is a valueless exercise remains. ISO 14001 registration is seen as a non-value-added process with uncertain benefits, and a “wait-and-see” approach among US industries have slowed acceptance of the standard nation-wide (Ruddell and Stevens 1998). Similar concerns have been raised over the related ISO 9000 standards for quality management, which were used as a model for the language of 14001, as the standards do not specify *how* to develop quality processes. Instead, they require only that a company define its own processes and document them, thus defining what the system is but not how effective the system will be (Kanji 1998). However, while 9000 has the advantage of being a requirement for international business, 14001 does not. Unless further studies are performed that support or deny the worth of the claims that 14001 certification is a paperwork exercise, the industry perception of 14001 will not change.

Towards this end, I have conducted an analysis of an individual company's certification process, in order to evaluate the validity of the concerns that ISO 14001 creates a “paper EMS.” A review of the process that the studied company underwent will demonstrate what, if any, significant changes to practices and procedures occurred that would ultimately

improve the environmental performance of the corporation, and help disprove the perception of the “paper EMS.”

Case Study Background: The ISO Process To achieve what is termed ISO 14001 certification or registration, a company undergoes a third-party auditing procedure from an ISO-accredited auditing agency. Generally, this begins with an internal gap analysis, which is a review of the organization’s current environmental management structure and a comparison of this structure to the line-by-line requirements of the standard. The gap analysis is then followed by the initial Phase I audit, a highly intense three-day inspection of the system and the facility by a qualified auditing firm. The company is given six months to correct all deficiencies found by the auditors. A Phase II audit at the end of the six months then primarily involves checking to ensure that all deficiencies have been answered. After this second audit, the auditors can recommend certification or rejection, or they can request additional changes be incorporated into the EMS. The auditors’ recommendation is presented to the country’s ISO representative, and the ISO representative will then finally approve or deny certification.

Once a site is registered under the standard, the auditors return on an annual basis to ensure that the EMS continues to operate efficiently and that all personnel are aware of their environmental responsibilities.

Case Study Background: Bayer Pharmaceuticals Bayer Corporation is a German chemical company with large facilities throughout the world. The Berkeley site is a member of the pharmaceutical division and is dedicated to the development and manufacture of biologically-based pharmaceuticals. Its primary product is Kogenate, Antihemophilic Factor (Recombinant), a protein used in the treatment of hemophilia. The site currently encompasses 30 acres in the industrial section of western Berkeley, although new property purchases will be increasing that size greatly over the next five years. Bayer Berkeley has over 1,700 employees and regular contractors, and is the largest employer and biggest facility in Berkeley outside the University of California campus. The site itself is not ISO 9000 certified, although it has adopted elements of TQM in its quality control and quality assurance procedures, and other North American Bayer sites have been certified under ISO 9000.

The site also has a well-established Health, Environment and Safety (HES) Department. The environmental division is made up of a Senior Environmental Specialist and an Environmental Compliance Intern. The Specialist reports to both site management and to the Corporate Environmental Control department that oversees environmental operations at all American Bayer facilities.

The Berkeley site began seeking ISO 14000 certification in June 1999, and was approved for certification after a series of audits in October 1999 and March 2000. This made the site the first Bayer facility in North America registered under the standard, and one of a handful of certified Bayer facilities worldwide.

Methodology: A Case Study Approach

I conducted a detailed case study of the ISO 14001 certification process from start to finish at the Bayer facility in Berkeley. According to Yin (1981), the "need to use case studies arises whenever: an empirical inquiry must examine a contemporary phenomenon in its real-life context; especially when the boundaries between *phenomenon* and *context* are not clearly evident." (Emphasis added) Because of the small number of businesses undergoing certification, the empirical case study methodology is the most appropriate method for gaining the best understanding of the phenomenon of ISO 14001. My position at the company of Environmental Compliance Intern allowed me to collect and analyze data as an "observing participant" which, according to Bernard (1995), is an especially valid approach for this type of study.

I have been working for Bayer's HES department since January 1999. While I primarily interact with the Senior Environmental Specialist, both my job duties and the design of the office contribute to my interaction with all members of the department on a daily basis. Other job duties ensure that I regularly interact with a large number of employees and contractors at various functions within the company.

My position at Bayer provided me with access to all necessary data about company policies, internal relations, and the ISO 14001-certification procedure from the "insider's" perspective. I was closely associated with the company's ISO 14001 certification from the starting point of the process. My supervisor and I coordinated the ISO 14001 Implementation Team, a small cross-departmental group that responded to all the Phase I

audit deficiencies within the six-month time frame and successfully underwent the Phase II audit. This vantage point gave me access to company documents and policies, and allowed me to conduct interviews and observations of daily interactions with staff members and the ISO auditors. I also had the opportunity to observe both of the audits, the site's response, the internal relations and politics surrounding the process, and the changes made to company practices throughout the time-period.

Throughout the study period I kept notes on interviews, conversations, and activity, then compared these notes to the results of four previous case studies on ISO 14001 in order to identify both key themes and experiences unique to Bayer. These notes were the primary source of materials from which I drew my conclusions.

Baxter Pharmaceuticals: A Comparison Case Additional information has been gained through interviews and site tours involving Baxter Pharmaceuticals, a competitor of Bayer's in the hemophilia therapy market. The Baxter facility in Hayward, California was undergoing 14001 certification during the same time period as Bayer, and their primary environmental specialist was interviewed to determine whether similar results could be found across different facilities. Because of my daily interaction with the Bayer ISO 14001 process, however, this paper will primarily concentrate on that single facility's experience.

Results

In June 1999, the Senior Environmental Specialist at the Bayer Berkeley site began evaluating the site's need for a better environmental management system. The Specialist chose to seek ISO 14001 certification as it represented the very highest level of proactive environmental management, and he felt that the site's strong environmental record indicated that it could successfully undergo the certification process. Over the next few months, the two environmental staff members conducted a gap analysis of the environmental programs. Using the ISO 14001 standard as a guideline, we assembled documentation for existing environmental management procedures, and created several new procedures as necessary. We then published everything in the site's first environmental manual, which essentially outlined the company's approach to environmental compliance on paper. The Senior Environmental Specialist then hired an independent consulting firm, Environmental Resource Management Certification and Verification Services (ERM CVS), to assess the site's

progress in October 1999. This firm was selected because of their recognized reputation as the best in the industry.

The auditors reviewed the system in place, and while noting that the site had a robust history of compliance, found ten major deficiencies in the EMS that had not been corrected by the paperwork generated during the original gap analysis. The auditors then gave the site a maximum of six months to correct all ten deficiencies, enumerated in Table 1 below.

Deficiency	Deficiency Description
Environmental Policy	Redevelop to reflect all environmental commitments
Aspects/Impacts	Develop strategy to determine which are most significant
Objectives & Targets	Must be related to the significant aspects/impacts
Objectives & Targets	Assign a responsibility, means and timeframe to each
Training	Develop mechanism to ensure that employees receive appropriate training
External Communication	Record decision for communication of environmental aspects
Supply Chain Management	Identify environmental aspects of goods and services used by site
Legal Compliance	Establish procedure to ensure compliance with environmental legislation
EMS Audit	Must conduct internal audit of the EMS
Senior Management Review	Must periodically conduct review of EMS by senior management

Table 1. Deficiencies Identified in Phase I Audit

In conjunction with the list of deficiencies, the auditors expressed their concerns that the environmental system was both too centralized in the HES Department and managed by too few employees: “many of the mechanisms in place are driven by the initiatives and efforts of a handful of individuals. Therefore, the primary concerns are related to the need for systems to be established which will ensure consistent and ongoing management of environmental risks” (ERM CVS 1999). The auditors not only wanted all line-by-line elements of the ISO 14001 standard incorporated into the EMS, but also sought assurance that the EMS would be more systematic, spread throughout the site, and able to survive the loss of any of the original environmental change agents who began the initiative.

To respond to both these needs, the Senior Environmental Specialist created the ISO 14001 Implementation Team, with representatives from HES, Materials Management, Information Systems, and Public Policy and Communications. The team was developed through the company's Quality Excellence Awards (QEA) program, which encourages cross-functional team formation in order to improve company practices and offers awards to the most successful team on each site. The team's sponsor was the site manager, which facilitated senior management investment and interest in the system.

To approach the tasks involved, the team first created an extensive Action List. Responsibilities and deadlines were assigned for all items on the list in order to ensure that the deficiencies were corrected. Then, using collaboration between departments and spreading environmental tasks throughout all job functions, the deficiencies and concerns of the auditors were addressed, and the final EMS was fully implemented.

While several of the deficiencies only required paperwork generation, most of the changes the team made required actual changes in job practices and organizational functioning. Examples are numerous, and include the following:

- A contractor auditing system has been established, and audits of all major on-site contractors are conducted quarterly;
- All major contractors now undergo an environmental training program and sign revised contracts with environmental rules before commencing on-site activity;
- Purchase orders for chemicals now include a statement regarding environmental control mechanisms;
- Senior managers are required to attend a review meeting twice annually in order to evaluate the system and suggest changes and improvements;
- Every employee on the site must now attend an annual General Environmental Awareness Training, which discusses hazardous waste and drain disposal rules, as well as their personal responsibilities in ensuring that the company meets its recycling goals and looking for potential improvements that could be made in the system; and
- Building engineers and managers are required to evaluate the environmental systems in their buildings, which has already led to proposals to replace an NaOH secondary containment system in the manufacturing area, and to redesign a water-use system that could potentially reduce water consumption by two-thirds.

The Implementation Team also developed a numerical system for reviewing and evaluating their environmental aspects and impacts, and an associated system for establishing environmental goals. The first set of these goals included completion of an analysis of hazardous waste generation in order to determine methods to reduce this waste stream, to directly approach one of the site's most significant environmental impacts.

The team also worked to communicate its findings and new practices, creating a press release and articles for external use, as well as an internal communications package for all employees. The site's environmental manual was updated to reflect all these changes and to provide the information necessary to understand the site's framework for the environmental management system. On site management, engineers, purchasing agents, trainees and other personnel were informed of their new duties, and site-wide environmental awareness training programs began.

The final ISO 14001 audit occurred on March 14 – 15, 2000. At the end of the two days, the auditing team announced that the Berkeley site had fully addressed all previous deficiencies in the system, and had demonstrated an outstanding level of environmental management, representing the commitment of the entire site to this standard. The lead auditor noted that this was an especially unusual outcome, as she had never before witnessed a company without any remaining deficiencies and ready for recommendation immediately after the second audit. The City of Berkeley also issued the site a proclamation recognizing the value of the company's achievement.

Further discussion with the ERM CVS team regarding the criticisms of ISO 14001 as a paperwork exercise revealed what may have been an important and unique circumstance in Bayer's process. The lead auditor noted that ERM CVS only performs ISO 14001 and other environmental audits. All other certifying companies in the US that she knew of had originally been ISO 9000 auditors, and have been approaching 14001 from the 9000 model, which, in her opinion, could more easily result in paper EMSs rather than actual working systems (Hosteny 2000, pers. comm.). This issue has been raised by ISO critics before, who worry that inconsistent approaches in the content and scope of certification audits could be problematic, and lead to a huge variance in ISO 14001-certified EMSs (Morrison *et al.* 2000, Gunningham and Sinclair 1999).

Discussion

Bayer's experience is particularly relevant to the discussion of "paper EMSs," as their original EMS had been largely created through the publication of an environmental manual. As the findings of the original Phase I audit demonstrate, the development of this "paper EMS" was not sufficient to register under the standard. Rather, the auditors insisted that they be shown actual proof of company-wide understanding of the EMS. This necessitated major changes in the structure of environmental management at the site. Originally, the site's environmental management had been handled entirely by the HES staff, which was essentially charged with maintaining compliance with all relevant legislation. Other than the permits and reports sent to environmental agencies, the staff needed to report its activities only to the corporate HES headquarters. As shown in Figure 1, the environmental staff could basically operate on its own, without interacting with the rest of the company beyond periodic environmental training sessions.

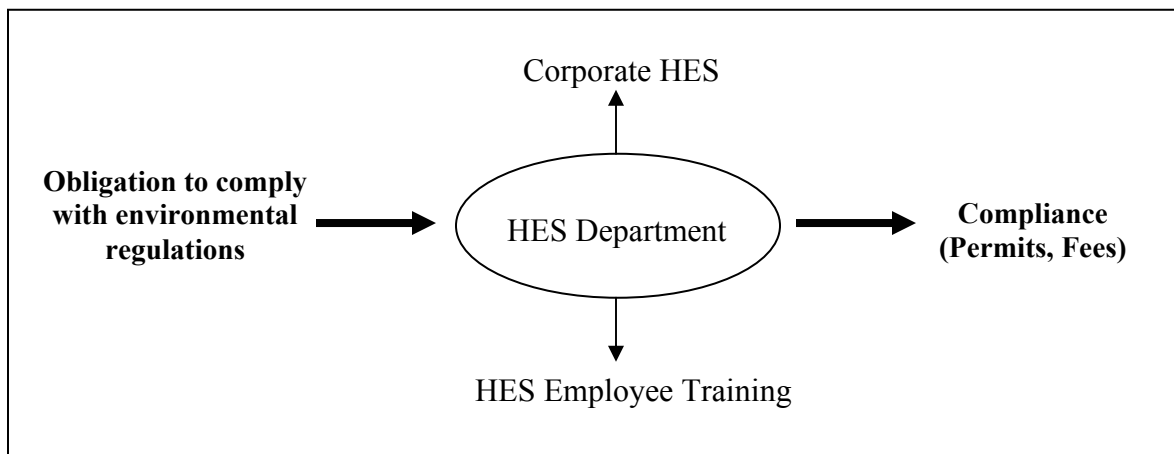


Figure 1: Environmental Management at Bayer before ISO 14001

However, as Figure 2 demonstrates, the nature of environmental management had to be extremely restructured in order to adhere to the auditor's requirements that the system not only comply with laws, but also continuously improve the company's environmental performance and integrate environmental responsibilities throughout the site. Various environmental tasks, such as insuring contractor awareness of our environmental policies, supply-chain management, and senior management review of the system are now handled by

Bayer staff in multiple departments. Continued interaction with almost all other parts of the company is now integral to the functioning of the HES department. Although HES continues to take primary responsibility for regulatory compliance-related work, several departments handle the additional tasks that go beyond the legal compliance requirements. This improves the system because should the Senior Environmental Specialist, the major change agent who pushed this initiative for the site, ever leave his position, there will be enough linkages in the system to re-route around his absence, and the system will remain intact and functional.

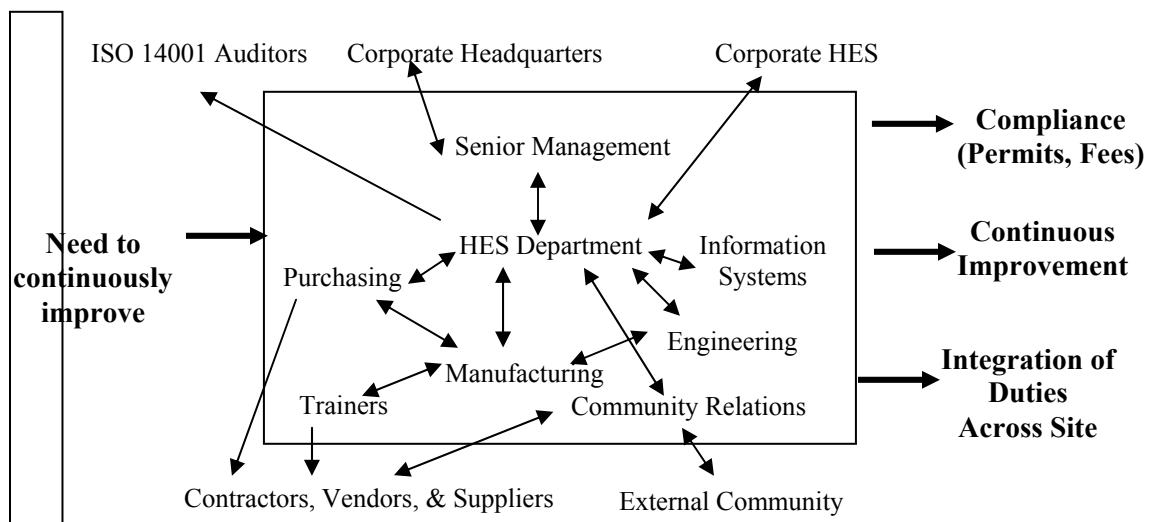


Figure 2: Environmental Management at Bayer after ISO 14001

The classic complaint regarding the ISO standards is that they are too procedural; conceivably, a concrete life vest could be manufactured to an ISO 9000-certified process but still be incapable of saving a drowning person (Gunningham and Sinclair 1999). However, these complaints focus too much on the language of the standard and overlook the power of the third party oversight. In the Bayer case, the ERM CVS auditors were highly critical of the company's initial environmental goals and plans for reducing the site's greatest impacts. While the standard itself only requires that an organization "identify priorities and set appropriate environmental objectives and targets," the auditors required that the goals push the company towards the highest industry standard (ISO 1996). The approach of the auditors reduced the possibility that Bayer could develop a "paper EMS" without actually changing and improving the company's environmental performance. However it must be kept in mind

that the company's efforts to create an actual system may have been largely driven by the requirements of the certification service that Bayer chose. Further studies to analyze the link between certifications causing significant or negligible environmental performance improvements and the approach of the organization doing the certification will likely find that this EMS-value/auditing body relationship is significant, as this aspect has not been studied previously.

Another significant aspect of Bayer's certification process may have been the motivation the company had for attempting ISO 14001 registration. The company as a whole was not interested in seeking certification and the site even faced resistance to adoption of the standard from the American corporate levels of Bayer. Environmental managers at the corporate headquarters felt that Bayer's commitment to the Chemical Manufacturers Association Responsible Care initiative was sufficient. It was also felt that ISO 14001 was an unnecessary burden; because customers of the pharmaceuticals products were not demanding it, there was no reason to seek an additional standard of practice. Therefore the effort had to be launched through the Berkeley environmental department acting on its own initiative, and was ultimately handled by individuals working as change agents with a desire to actually improve the environmental performance of the company.

Baxter: Findings and Analysis Similarities in motivation can be found in the Baxter Pharmaceuticals case. Although the Baxter effort was launched on a company-wide basis, it was not driven through a desire to match the 9000 certification or through customer demands. Rather, Baxter had been embarrassed by several highly publicized spills and fines for Superfund sites, and was hoping to change the public perception of the company to be perceived as more environmentally friendly. Additionally, the company's management had recently been transferred to Vienna, Austria, and top management had embraced the pro-environment approach more typical to European corporations. The company began a system of reporting on its environmental performance to the public and introduced the ISO 14001 system to all of its sites, supporting the effort from environmental rather than managerial or TQM motivations. The resulting EMSs that have been developed have been highly effective in improving Baxter's environmental record, and are in no way perceived by the staff involved to be "paper EMSs" or bureaucratic exercises (Miles 2000, pers. comm.). Baxter

did not focus on ISO 9000 or on creating paperwork, but rather worked to create an auditable system that will prevent additional embarrassing environmental incidents from reoccurring.

Similarities in the Findings The similarities in original motivations for seeking ISO 14001 certification, and the success of both Bayer and Baxter's EMSs may indicate that organizational motivations may be an important factor in creating value in an EMS. Other companies, including other Bayer sites, are attempting certification under the standard because their customers demand it, or are driving the initiative through the quality assurance departments to best correspond with their 9000 certification. These may be the companies most prone to creating procedural EMSs that document already occurring behaviors within the organization, without taking the extra steps to ensure continuous improvement and assure the very top tier of environmental performance. If, however, organizations take the alternative route of implementing ISO 14001 as a means of expressing their desire to perform better environmentally, they will most likely be more prone to use the standard as a basis of inducing comprehensive environmental change.

Conclusion

The significant number of deficiencies at Bayer found by the auditing team after the Phase I audit, as well as the extreme changes that needed to occur before the company could be certified, demonstrate that the Bayer Pharmaceuticals Berkeley site could not have been ISO 14001 certified after simply creating a "paper EMS." Rather, the company had to significantly re-organize its approach to environmental management, and then had to communicate these changes through increased environmental training, site-wide announcements, and enacting supply-chain and contractor management. The goal of this process was to change the mindset of employees so that environmental activities were not considered external to their basic job duties, nor the responsibility only of a stand-alone HES department, but rather as an integral part of their own daily responsibilities. An environmental review committee, EMS auditing service, and annual senior management reviews were established to ensure continued interest in and improvements to the system.

A review of the Bayer experience has revealed two key points that may have prevented the site from simply building a paper EMS for use only as a publicity tool: the environmental focus of the auditing body, and the motivations of the company in seeking the certification.

Bayer was unable to use its past environmental record and the publication of its environmental manual to guarantee its ISO 14001 certification because of these two drivers. However, the concern that ISO 14001 certifications are essentially paperwork exercises is an indication that the problems both of auditing bodies with little or no environmental expertise and of organizations with misplaced motivations for seeking the standard may be widespread.

A major recommendation that this study generates is the need to strengthen the ISO 14001 third party certification process to ensure that auditing is carried out with a strongly environmental focus. The auditors must use the language of the standard as the very baseline of what a company must do to be certified. Then, because the standard is by necessity vague and does not require specific pollution abatement measures, auditors must use their knowledge of the specific industry or organization's capabilities to require the highest possible level of environmental performance. Morrison *et al.* (2000) have reached a similar recommendation, stating that accreditation bodies must, at a minimum, ensure that audits are carried out in a consistent manner, and that the auditors have backgrounds in environmental regulations, design, or sciences. This suggestion is particularly important because, as the ERM CVS auditor noted, what largely prevents certification from being a paperwork exercise are the instructions and recommendations from the auditors.

A useful guideline for companies to ensure that their ISO 14001 certification attempt is successful and that they build a system that will produce value for the company, is to (1) begin with an auditing service that focuses on environmental aspects and has personnel qualified to evaluate the environmental engineering and science-related components of the EMS; and (2) drive the initiative through internal personnel that are genuinely interested in improving the current system and decreasing the environmental impact of the company on its surroundings. This will lessen the possibility that the EMS that is created will have little to no impact on actual processes and procedures within the organization. Because it has to be applicable to every sector of business and industry in every country in the world, the language of the ISO 14001 standard lacks specific requirements for performance. If taken at face value, the standard can be used to create a "paper EMS" that results in no actual on-the-ground change for the organization. However, strengthening the auditing process in order to apply the standard to its fullest extent, and basing the system on multiple personnel that share

the desire to improve the organization's environmental performance may best serve to create a cyclic EMS that extends beyond compliance to continuous improvement, using the potential offered by the ISO 14001 standard to its fullest extent.

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