ISO 9000



SEEKING RECOGNITION: U.S. AUDITORS BUILD THEIR BASE

Backlog develops in a rush to register

The system for accreditation of ISO 9000 registrars in the U.S. is still in a state of flux. No one organization has sole authority to anoint a registrar, but reputable registrars usually seek the recognition of either the private sector Registrar Accreditation Board (RAB; Milwaukee) or one of the European organizations that confer accreditation, or both. In addition, the U.S. Commerce Dept.'s National Institute of Standards and Technology (NIST; Gaithersburg, MD) has proposed establishing a Conformity Assessment Evaluation (CASE) program that could include ISO 9000 accreditation supervision or harmonization.

For chemical companies, there are a number of information sources available that can help sort out the issues at various levels of involvement in ISO 9000. One resource, particularly appropriate for small companies or those just dipping their toes in ISO 9000 waters for the first time, is the Chemical Manufacturers Association (CMA; Washington) Total Quality Council's new pamphlet, "Criteria for Continuous Improvement" (CCI).

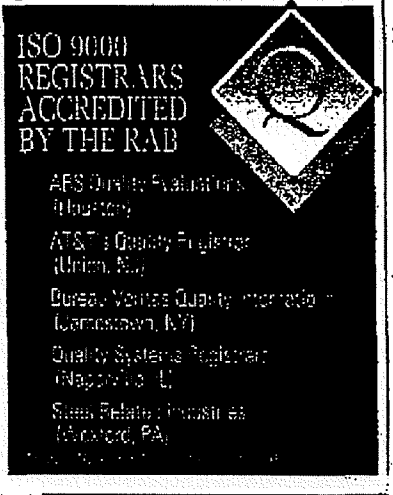
In question-and-answer form, CCI attempts to help a company find common ground when confronted with audit requirements in overlapping areas, including ISO 9000, Responsible Care, and application for the Malcolm Baldrige National Quality Award.

Francis Jackson, director of quality planning at Eastman Chemical (Kingsport, TN) and member of the CMA task force on total quality improvement, says that CMA is promoting a standard, simplified criterion by which a company can evaluate itself or a supplier, or provide quality assurance to a customer. "Eighty percent of the needs under these various programs are common," Jackson says. CMA is in a leadership role on simplification, and other industry associations and RAB are meeting with the CMA task force.

EUROPEAN CRITERION. RAB, a three-year-old private nonprofit organization, accredits North American registrars. Accredited registrars pay a fee for the qualifying audit, plus an ongoing fee (based on the volume of business) entitling them to use the triangular RAB seal on the ISO certificates they award. George Lofgren, RAB's president, says his organization requires the registrar's audits to be based on internationally accepted criteria, particularly the ISO/European Community Guide 40, as well as EN 45012. "There has been some criticism of adopting a European criterion, but it's the practical thing to do—Europeans are ahead of the rest of the world on this," Lofgren says.

However, many active ISO registrars in the U.S. are not accredited by RAB. Although some of them work closely with RAB and its parent organizations—the American Society for Quality Control (ASQC; Milwaukee) and the American National Standards Institute (ANSI; New York)—others may not. Some registrars are also accredited or recognized by one or more of the European accreditation bodies. In addition, ANSI and RAB have signed a memorandum of understanding declaring their intent to work toward a mutual recognition agreement with the Raad voor de Certificatie (RVC) in the Netherlands.

The European Community has established a system whereby each national government designates "notified bodies" to accredit ISO 9000 conformance assessment registrars. The notified bodies then authorize and supervise auditors who issue ISO certificates. Because European notified bodies are all designated by government agencies, there has been some concern



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regarding the lack of government involvement in the U.S. registrar accreditation system. Accordingly, NIST published a request for comments on the proposed CASE program in the March 27, 1992 Federal Register.

The language proposes that NIST establish a conformity assessment system comparable to RAB's. According to the CASE proposal, "The [registrar accreditation] process will be initiated by voluntary application by an entity, payment of fees, quality system evaluation, quality document evaluation, onsite assessment, final evaluation, and approval decision. Participation will be voluntary and open to all entities which desire NIST recognition in the areas offered." While CASE could turn into a government blessing of the private sector efforts at RAB, industry sources fear that NIST could well set up a program that competes with the accreditation board.

The comment period on the NIST CASE proposal closed on Sept. 30. NIST's decision on the degree to which the U.S. government will get involved in the ISO registrar accreditation process could be ready by the end of the year, but most observers are expecting a public announcement next year.



Lofgren: Global harmony.

CMA is among the many organizations that have submitted comments, saying, "CMA recognizes the need for the U.S. government to play a role in organizing the U.S. conformity assessment system, especially in response to [European Community] requests for government assurance of the competence of U.S. conformity assessment bodies. However, this government participation should be limited to the minimum necessary."

The CMA comments, like those of many other interested parties in the U.S., express concerns that CASE would duplicate RAB's existing program: "Private sector developments at the conformity and accreditation levels make it unnecessary for government programs involving certification or accreditation. As a result, NIST's CASE program should focus on the recognition level, where our trading partners have requested government-to-government assurance of the competence of U.S. conformance assessment activities," says CMA.

ANSI, the U.S. member body of the ISO, has also commented on the NIST CASE proposal. "ANSI serves as a policy forum and information resource," explains v.p. George Willingmyre. "We are a multiconstituency membership organization, including about 1,500 companies of all sizes; organizations and associations [including CMA and ASQC]; and government agencies, including the departments of Defense, Commerce, Energy, and the Environmental Protection Agency."



Jackson: A common standard.

ANSI emphasizes the effectiveness of market-driven forces in streamlining the accreditation process. Willingmyre says, "We agree with NIST's intent—to enhance U.S. competitiveness—but question that government recognition will contribute to that. We don't want to see the government compete with the private sector, but rather to work with it. There is a role for government-to-government activity, but government oversight of the accreditation process will just add another layer of bureaucracy."

Registrars also express some alarm at the CASE proposal. Elizabeth A. Potts, president of registrar ABS Quality Evaluations (ABSQE; Houston), says, "I concur with NIST and the Department of Commerce wholeheartedly that there needs to be some U.S. government involvement, but NIST shouldn't duplicate the private sector." Potts points out that her firm pays a percentage of its revenue to each accreditation bureau that recognizes ABSQE every time the registrar uses the bureau's seal. Currently, both the RAB and RVC seals can appear on ABSQE certificates. She has been hoping for mutual recognition agreements that will allow ABSQE to pay one fee for global recognition. The last thing she wants, she says, is a proliferation of accreditation bodies all demanding fees.

"NIST should act as the government recognizer of the private sector mechanism," agrees Richard Kleckner, president of RAB-accredited Quality Systems Registrars (QSR; Naperville, IL). "It should stay out of the accreditation business. You don't need to reinvent the wheel."

While some of NIST's CASE proposal may be less than welcome in the private sector, most agree that international harmonization of standards is desirable. In addition to the ANSI/RAB memorandum of understanding with the RVC, RAB is seeking relationships with other European organizations, including the association of European accreditors, the European Accreditation of Certification Council (EAC). RAB's Lofgren also notes that Australia and New Zealand have established their own program under the Joint Accreditation System for Australia and New Zealand (Canberra, Australia).

"We want a worldwide harmonized system," says Lofgren. "Our prime goal is mutual recognition," although he admits that so far that has been difficult to achieve. One reason is "the wide variability in the maturity of the organizations," he says.

Global harmonization is one purpose of "a movement afoot to form an association of U.S. registrars," says Peter B. Lake, of Steel Related Industries Quality Systems Registrar (Wexford, PA). Government involvement may also be called for to facilitate mutual recognition agreements.

SIC CODES. Under the existing private sector accreditation process in the U.S., only five registrars have received the right to use the RAB seal (*box, p. 30*). "The RAB evaluation process depends on the skills of the people doing the audits. We focus on their competence," says Lofgren. The RAB authorization letter lists the Standard Industrial Classification codes of the industries for which the registrar is deemed competent to conduct ISO audits. RAB will send a list of names and addresses of registrars to interested parties. The list includes many that are not accredited by RAB but have worked with it.

With the interest in ISO registration running high, a bottleneck has developed with demand for registrars exceeding supply. Some companies may have to wait six to nine months before they can schedule preaudits with their chosen registrar. RAB expects to double the number of registrars it has accredited within the next year, although only one was approved in the past six

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months: Steel Related Industries. "While the bottleneck will get bigger, the interest in registration is still growing very rapidly," says Lofgren.

"RAB can provide bona fides for an American registrar that may have less experience than its European counterpart," Lofgren notes. Steel Related Industries may be one example. A nonprofit organization with a long history of related activities, the firm has yet to issue its first chemical industry certificate; but unlike many other qualified registrars, it has no waiting list. According to Lake, Steel Related Industries is also seeking European accreditation directly through the RVC. "Steel Related Industries is an especially appropriate registrar for chemical companies with steel industry customers," says Lake.

QSR already has dual accreditation with RAB and the RVC. "The two accreditation processes are very similar," says QSR's Kleckner. "It's a significant marketing advantage" to have the blessing of both. "Several companies waited for the RVC accreditation to come through before signing on with us." QSR has issued certificates to quite a few chemical companies, including Amoco, Degussa, Great Lakes, OxyChem, Texaco Chemicals, and Witco.

A little more than one-quarter of ABS Quality Evaluations' business comes from the process industries, says ABSQE's Potts. The registrar, which has dual RAB/RVC accreditation, also has a sister company based in London that is pursuing accreditation by the National Accreditation Council for Certification Bodies.

William M. Dorman, v.p./operations at Bureau Veritas Quality International (BVQI; Jamestown, NY), an affiliate of London-based BVQI Ltd., has issued certificates at two U.S. chemical locations—an Akzo plant in Deer Park, TX and a Copolymer Rubber & Chemical plant in Baton Rouge, LA—and is working with others now. "U.S. companies requested RAB accreditation," Dorman says.

Underwriters Laboratories (UL; Melville, NY) is not accredited by the RAB, "but we are working very closely with it," says Michael J. Caruso, UL manager/ISO 9000 registration. UL has issued certificates at 70 to 80 chemical locations in both the U.S. and Canada, including sites for Du Pont, Union Carbide, Hoechst Celanese, and ICI. UL coregisters with the British Standards Institute, Canada's Quality Management Institute, and the Japan Management Institute. It also has multiple U.S. auditor locations, including Northbrook, IL; Santa Clara, CA; and Research Triangle Park, NC.

Plants that have received their ISO certificates are less worried about the accreditation body than they are about the quality improvements that the registration process has engendered.



Potts: Don't duplicate RAB.



Kleckner: Dual accreditation.

"From the customer's perspective, the key is that your quality assurance system has been reviewed by a third party. Who that third party is doesn't seem to be as much of an issue as some may have thought," says Barbara Kildau, North American quality systems manager for Dow Chemical (Midland, MI). Westvaco chemical division (Charleston, SC) Total Quality manager Jerry E. McDowell agrees. "You don't want to worry too much about the subtle differences between registrars," he says.

FULL PLATE. With most registrars having a full plate doing audits and preaudits—and ISO guidelines prohibiting preauditors from profiting from consulting companies—a large number of consultants have become involved in helping to formulate quality strategies that include ISO registration and to prepare for the registration process. Issues addressed often include which registrar to use, what sites and products to register, and whether to go for multisite registrations, as well as what documentation and procedures might gain from upgrades before submitting to an ISO audit.

"Until they get mutual recognition squared away," says Al Chamberlain, manager of Andersen Consulting (Chicago), "we recommend that clients go with the registrar where their customer is." Chamberlain also stresses that very few companies get their ISO certificate on the first pass, even with fairly extensive preparation. "You should use your registrar to do the preaudit if your primary motive is to get the certificate," Chamberlain says. "But if you're really after quality improvement, you should go for as many eyes as possible," including preaudits by consultants who are not constrained from making recommendations on how to fix problems.

Nonetheless, most companies pride themselves on avoiding outside contractors when it comes to the actual documentation needed. "You don't want a consultant to write your documents for you," explains UL's Caruso. "ISO registrants need to document what they do and do what they document," and it's difficult to sustain standards someone else has set.

RAB's Lofgren notes that consultants are not subject to the RAB's governing standards. "We have our hands full with what we're doing now," Lofgren says—accrediting registrars. "We don't work with preaudit consultants." Consultants sometimes offer conflicting information on ISO 9000. Information sources that can help resolve such conflicts include ANSI and NIST. Most registrars check with them regularly. "NIST has been outstanding in information services," says ABSQE's Potts.

Most consultants, like most registrars, base their fee structure on the headcount at the sites being reviewed, as well as which ISO standard is at stake. "Ninety percent or more of process companies go for 9002," Chamberlain says. Chamberlain characterizes process industry audits as relatively routine compared with those in more labor-intensive industries. "They're better documented to begin with," he explains.

While ISO registration requirements are applicable across all industries, some issues have particular relevance to the chemical industry. UL's Caruso emphasizes document control. "Document control is a problem in all industries in the U.S., even where there is already good documentation," he says.

"The scope of the registration" is the critical issue for most chemical companies, says ABSQE's Potts. "Should you include distribution, warehousing, purchasing, sales offices? That depends on how the company is structured."

Another issue that comes up more frequently at chemical companies than in other industries is "calibration of instruments," says BVQI's Dorman.

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