ISO 9002: how we did it

Mark Berenson

SCM's corporate culture now is more structured and disciplined, and the company does a better job of meeting customer needs.

The ISO 9000 series of standards is being used by many companies around the world to establish whether their suppliers have in place a quality management system that ensures the supplier's ability to meet its customers' product and service needs. Supplier quality management systems are audited by qualified outside, third-party assessors. If approved, a supplier's system is said to be "certified" and the supplier becomes "registered" as an ISO 9000 supplier.

SCM Chemicals' Baltimore operation was registered to ISO 9002 in September 1990. ISO 9002 registration is one tangible result of our broad-scale quality improvement effort. This is how we did it.

Background

ISO 9002 had its beginnings in the early 1980s, as the 12 European Common Market countries realized that their alliance would make them competitive in size with the other economic entities in the world. They also realized that something would have to be done to improve the quality of their products and services. Quality was viewed as an absolute imperative for the success of the European Common Market in 1992.

England was the first to adopt quality standards and was quickly followed by a number of other countries. In 1987, the International Organization for Standardization (ISO) extended its global umbrella over the various national quality standards that had been developed, and the ISO 9000 series of quality standards was born.

ISO 9000 itself is a guideline for the selection and use of each of the following standards:

- ISO 9001 is the model for quality assurance in "design/development, production, installation, and servicing." This standard applies to the most highly integrated companies, which depend on research and development efforts to bring to market a frequently changing product line.
- ISO 9002 is concerned with "production and installation" only, and applies to the activities of most companies in the world today.
- ISO 9003 involves "quality assurance in final inspection and test," and relates to the simplest manufacturing operations and resale businesses.
- ISO 9004 offers guidelines for the application of the standards to actual operations.

Today, ISO 9002 is generally recognized around the world as *the* international standard for quality management.

During the mid- to late-1980s, SCM Chemicals, like many other companies, was seeking to strengthen its quality program. We listened to what Deming, Juran, and Crosby had to say. We talked to consultants. We tried statistical process control. We felt we were doing all the right things, but the goals still seemed elusive. At times, the paths to achieving those goals were downright obscure.

After careful study, we liked what we saw in ISO 9002. The things ISO 9002 told us to do made good sense. First, we all had to get involved, as with Total Quality Management. Second, we had to write procedures and instructions, and then we had to follow them. Third, we had to be rated against a worldwide standard by independent auditors. ISO 9002 registration seemed to steer us in a clear, specific direction.

Documenting the system

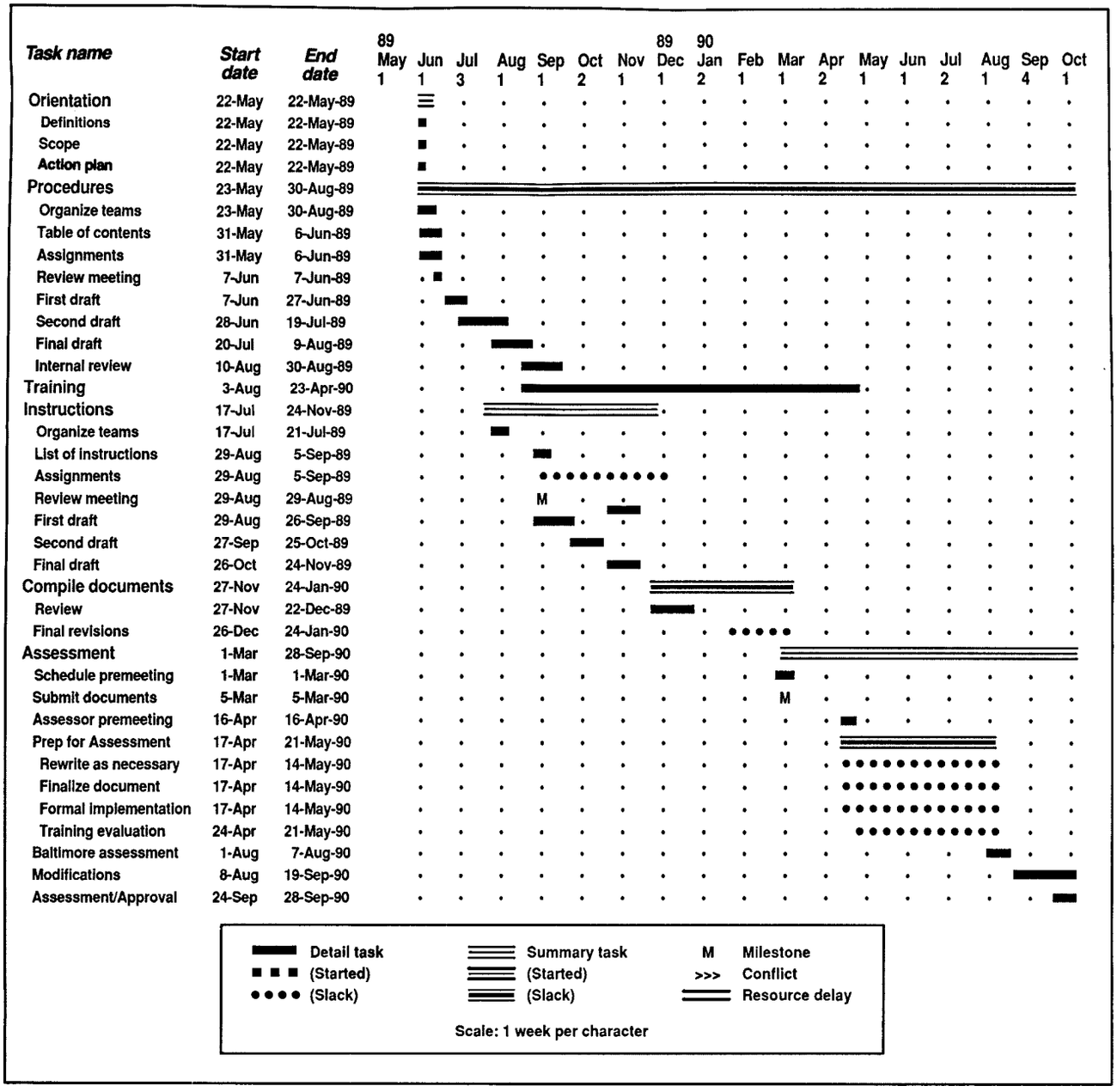
SCM Chemicals' approach to ISO 9002 registration is outlined below:

- Management commitment
  Company policy statement
  Resource allocation
  Appointment of coordinator
- Documenting the system
  Structure (ISO 9002 requirements, quality manual, procedures, and instructions)
  Internal review
  Authorized approvals
  Controlled distribution
- Operating the system
  Employee awareness training
  Compliance with documentation
  Internal auditing (training of auditors, audit schedule, audit reports, and corrective actions)
  Periodic independent audits
- Management review
  Audit participation
  Audit reports
  Steering committee.

It made sense to us to seek certification on a site-by-site basis, beginning with Baltimore. The target date for

Berenson is director, quality assurance, at SCM Chemicals, Inc., 3901 Ft. Armistead Rd., Baltimore, MD 21226.

1. Quality system implementation schedule



registration of our quality management system was Oct. 1, 1990, about 18 months away. The biggest part of the job, obviously, involved writing. We began by putting together a quality assurance manual that stated our corporate policy and described our quality mission: ". . . to implement a system for the economic manufacture of quality products and services that conform to specification and meet customer expectation."

Each senior manager established his leadership role by describing his department's function and general responsibilities his people would have in the new quality management system. In all, the manual was about 50 pages long. It set the tone for the supporting procedures and served as inspiration and guiding light for the program.

The rest of our documentation needed to be organized and updated. We had a process control plan, policies, procedures, instructions, and test methods for most of the routine things we did, but some were outdated, a few were lost, and one or two had been forgotten. Coordination between them was minimal. A mechanism for making changes had to be established, and files for master copies of all documentation had to be set up. The job seemed enormous.

So we did the sensible thing: we formed a team. This was not the first cross-functional team at SCM, but it was certainly the largest one in company history. It was apparent that we were all going to have to work together to get the job done. The team met informally every week for about an hour to discuss problems, to answer questions, and to clarify the differences between procedures and instructions (procedures explain *who* does what, while instructions provide the details of *how* those responsibil-

ities are met). The minutes from each meeting were distributed to attendees and to senior management.

We developed the project schedule shown in **Fig. 1**. Then, we assigned responsibility for each of the functions required by our quality management system to specific individuals from appropriate departments, and requested first drafts in six weeks.

The structure of our quality management system is shown in **Table I**.

Beyond the minimum requirements of ISO 9002, we chose to include such things as maintenance and information systems. We realized that there was no way we could produce a uniform, high-quality product without a consistent, smooth-running operation, so minimizing unscheduled shutdowns was a clear objective for quality improvement. As our dependence on computers increased, we also realized that we had to provide for maximum reliability of both hardware and software: we never wanted to excuse a mistake by saying "Oh, that was a computer error."

We felt strongly, too, about the use of statistics. In fact, much of the improvement we've observed in the quality and uniformity of our products is due in no small part to the application of statistical analysis and improved process control systems. ISO 9002 refers to the "appropriate" use of statistical methods as though they were optional. We viewed them as absolute necessities.

We chose not to include an accounting system for tracking costs of quality. A "cost-of-quality" program is not a specific requirement of ISO 9002, and we felt that the success of our quality management system should be measured in terms of customer satisfaction, not corporate profits. If customers' needs are met, profits should follow.

As drafts were reviewed and discussed, we began to see how departments interfaced with each other. We could see who was responsible for what and who was not responsible for what. In one case, we found that two people in different parts of the plant were responsible for the same thing (ordering pallets). Over the years, some people had absorbed responsibility, while others had shirked it. The organization of work responsibilities had evolved, to some extent, on the basis of personalities rather than by assignment. Our first discussions of better ways to do things grew out of the internal review sessions. In many cases, new and better procedures evolved from this kind of peer review process.

Once the procedures were written, we began to organize the supporting instructions, the nitty-gritty details of how to get things done. Test methods suddenly became instructions, as did sampling schedules, finished product specifications, process control plans, product recipes, operating parameters, preventive maintenance plans, and standard operating procedures. In a few cases, instructions had to be written entirely from scratch. Drafts were checked by operators to be sure that written instructions truly reflected the best way of doing things. Finally, the documents were all numbered and referenced according to the structure outlined in Table I.

Along the way, we stopped occasionally for a "reality check" to be sure we were on the right track. We were aided in no small part by a consultant and by our operation in Stallingborough, U.K., which had become registered to ISO 9002 in August 1989.

Training and auditing

We also paused for training on two fronts: general awareness training and internal audit training.

The awareness training helped to let employees know about ISO 9002 and our new quality management system. It was important to explain the rationale for the program and to have them "buy in" at an early stage of its development. We wanted them to feel a sense of involvement rather than just having another new program imposed on them.

Internal auditing (another peer review process) came to have a vital influence on the quality management system. Again, employees from all walks of life were involved. They came from different departments and represented different levels of responsibility. Fourteen auditors were trained by our consultant. They formed teams, developed an audit schedule, and then went to work.

Their mission was clear: to bring our documentation—and our compliance with that documentation—up to the levels required for ISO 9002 registration. We were careful not to present the internal auditors as an internal police force. During the first round of audits, in fact, the internal auditors acted as advisors. Then they started to get tough. Tough, but fair.

The results were gratifying. No one wanted to be the reason for failing our formal ISO 9002 assessment in August 1990. With audit reports reaching the senior management level, people became very cooperative. Fresh eyes flushed out a number of problems that hadn't been seen before. Some problems were handled quite simply: grammar, spelling, cross references, etc. Others, though, such as the one concerning our handling of special customer requirements, forced us to devise entirely new systems.

Operating the system

Once the documentation was written and people were informed as to what was expected of them, the focus shifted to compliance with the procedures and instructions. If it was written down as a procedure or instruction, then it had to get done and someone had to be accountable.

An interesting requirement of ISO 9002 concerns the prohibition against photocopying controlled documents (with only certain carefully defined exceptions). The purpose of this provision is to ensure that only current documents are in use, thereby eliminating situations where outdated procedures, instructions, or test methods may be used. We quickly realized the consequences of an analytical technician continuing to make 40-mL additions (according to his old test method), when everyone else was adding 50 mL (as required by the new method that was issued the week before). Unauthorized "cheat sheets" at the lab bench, on control room bulletin boards, and on instrument panels are strictly prohibited, basically because their currency cannot be assured.

Another interesting provision of ISO 9002 is the one involving a process change. Our quality management system requires that changes be made only in a certain controlled manner. That manner ensures that the change is made on the basis of the best available information, that it is properly authorized, that all appropriate personnel are informed, and that the effects of the change are

carefully monitored and documented. This represented a cultural change in some parts of our organization, but it was certainly a change for the better. We no longer have approved changes made during the A shift being undone by an uninformed operator on the B shift.

ISO 9002 is very particular about corrective actions made in response to customer complaints. Our system for handling customer complaints was upgraded to conform to ISO 9002 requirements. Our system now ensures the customer a response within five working days. Further, it requires an explanation from the responsible department, along with recommendations for corrective action to be sure that the problem does not recur. Still further, our system requires that the corrective action be monitored to be sure it was truly effective in preventing a recurrence. Finally, there is a provision for management review and analysis of customer complaints on a regular monthly basis.

The assessment

Our assessment for conformance to the requirements of ISO 9002 was carried out in August 1990 by Yarsley Quality Assured Firms Ltd. of Manchester, England. We chose Yarsley primarily on the basis of its status as an internationally accredited certifying body. A few companies in the United States had declared themselves in the business of doing ISO 9002 assessments, but they had no international standing, and we wanted our ISO 9002 certification to be as strong as possible and to withstand any possible challenge.

Two men spent three days auditing our Baltimore operation. They were more thorough than we had imagined. They were tougher than we expected, but entirely fair. If we said in our procedures and instructions that we were doing certain things, they expected to find evidence (records) of those things in our files. They were like a pair of bulldogs: once they posed a question, they never let go until they had an answer.

Our certificate of registration was approved on Sept. 17, 1990.

We did not achieve a perfect score, however. In fact, Yarsley found a few minor concerns that required corrective action. They were back in six months, and as part of their regular surveillance visits, checked to be sure those corrective actions were fully implemented. During this time, they also audited selected parts of our Quality Management System in greater depth.

Aside from the honor of being the first manufacturer of TiO_2 pigments in the United States to have been registered under ISO 9002, we consider the implementation of a quality management system to have been extremely beneficial from an internal standpoint.

A lot changed during the 18 months it took to build our quality management system. Our culture has changed, and continues to change. We believe in ourselves as a quality organization, able to provide quality products and services. We have lowered interdepartmental barriers, and have learned to work together in cross-functional groups. We are a more structured organization today than we used to be; we are more disciplined. We are doing a better job of meeting our customers' needs, and we are now recognized as quality leaders. We're ready for 1992.□

I. Quality Management System elements

	Procedure assigned	
Management of QA Systems	QManual	MEB
Document control	1	MEB
Quality system review and audit	2	MEB
Sales/Marketing procedures	3	CDA
Order processing	4	SAC
Project engineering and design	5	WEB
Purchasing and vendor relations	6	JDP
Receiving		
Ores	7a	DHG
Raw materials	7b	ETC
Supplies and spare parts	7c	MFM
Production planning	8	GTL
Process control and production		
Chloride	9a	RHW
Sulfate	9b	AFP
Plant services	9c	RHW
Raw materials—ordering and distribution	9d	ETC
QC, product inspection and assessment	10	DJH
Quality control	10a	DJH
Finished product testing	10b	DJH
Analytical services	10c	HCG
International test methods	10d	WAB
Corrective action/engineering change	11	SRS
Planned changes	11a	SRS
Off-hours changes	11b	SRS
Plant trials	11c	SRS
Process control plan changes	11d	SRS
Operating instruction changes	11e	SRS
Major process changes	11f	SRS
Minor process changes	11g	SRS
Maintenance	12	MMS
Oxidation	12a	MMS
Moore filtration	12b	MMS
Instrument calibration	12c	MMS
Packaging and distribution	13	DHG
Packing	13a	RHW
Warehousing	13b	RNP
Allocation	13c	JRT
Distribution	13d	DHG
Technical service	14	JSG
Sales service	15	JAM
Customer complaints	15a	CAC
Pricing	15b	MJG
Special instructions	15c	DHG
Freight rates	15d	DHG
Product specification review	16	CDA
Training	17	LRV
Information systems	18	RJB
Public engineering standards	19	NJF

The author would like to thank D. E. Knapp for having the courage to go forward, R. V. Pearse for his wisdom, and V. J. Mazza for his faith that it could be done.

Received for review July 2, 1991.

Accepted July 12, 1991.

Presented at the TAPPI 1991 Process and Product Quality Conference.