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# ISO 900: MAKING QUALITY HAPPEN

INDUSTRY, SCIENCE AND TECHNOLOGY CANADA
SERVICES TO BUSINESS BRANCH
AND
DEVON HUNTER CONSULTING

PREPARED BY MURRAY HUNTER May 1993, Issue 2

ISO 9000: MAKING QUALITY HAPPEN



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SERVICES TO BUSINESS BRANCH
AND
DEVON HUNTER CONSULTING

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#### **Preface**

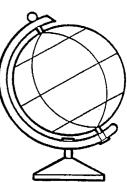
ISO 9000 is the definitive benchmark for evaluating the quality of management in any organization, large or small. This booklet explains what it is, what the benefits are and how to get started.

Seven companies, ranging in size from about 40 employees to Canada's largest, agreed to participate. I want to thank them for graciously making their staff at all levels available to me, in the interests of Canada's prosperity. I also want to thank the people who use ISO in their daily work, who helped make this information accessible by talking from their own experience about ISO in practice:

I particularly want to thank the organizations and individuals listed below. Industry, Science and Technology Canada (ISTC) for providing partial funding; Karen Burke and Astrid Prud'homme for inspiration and brainstorming; Bruce Bennett at Bell Northern Research; Lilah Houeye and Karen Oliver at AT&T; Bruce Mathewson at Kodak Canada; Marni Ferguson, Paul Meyer and Mickey Jawa at Monsanto Canada; Ian McKechnie at Mitel; Liam Cullen at ABE; Scott Henry at LPB; and Thistle Group for layout.



# OVERVIEW OF ISO 9000



#### Overview of ISO 9000

#### **Assuring Quality**

Excellence in service is never accidental; it is a product of focused attention on satisfying customers. To satisfy customers, on time and within budget, this attention must be focused on the way the organization is set up. Quality assurance aims to set up the organization so that it can satisfy its customer. It does so by reducing errors and waste, and by focusing the organization's activity on producing what is valuable in the eyes of the customer.

#### **Standards-based Quality Assurance**

Although each customer is unique in some ways, as is each organization and its environment, every effective system of assuring quality has some elements in common. A standard vocabulary has evolved to describe these common elements of internal management, and a set of categories for analyzing them. Because these elements and categories are common and standard, they can be used to set up or to study any organization that provides service. This makes every organization's best practices accessible and useful to others, even to those in a different field.

A check list to evaluate organizations under each of these categories has developed under international agreement, and has proven very useful for identifying in advance whether an organization can be relied on to produce quality in its products or services. To make this process of verification easy to use, international bodies have agreed on a system of third-party certification that is the same the world over.

By speeding up contracting and promoting successful transactions, this certification is the practical face of world trade. As more people observe its powerful benefits for clients and for the effectiveness of organizations, standards-based quality assurance is quickly spreading to other organizations even if they are not based on exports, and it is likely to soon become a basic feature of good management throughout the world.

#### The Quality Standard

This international quality standard is called ISO 9001, and was accepted by 37 countries in 1987, after many years of joint development through the International Organization for Standardization (ISO), based in Geneva, Switzerland. Its use spread quickly. By late 1991, for example, 16,000 companies in the U.K. alone had been certified to it, and much of the trade within and into Europe now requires certification of the supplier as a

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Overview

prerequisite for bidding on contracts. As a result, North Americans have become very interested in certification to ISO 9000 in order to protect their markets abroad. Many of the major corporations that deal with Europe, such as DuPont, AT&T, Monsanto and Northern Telecom/Bell Northern Research, have begun or have completed implementation of ISO 9000.

The standards are the product of international negotiations, and Canada has been a leader in the development of the standards, working with the national standards organizations of 91 other countries, such as ANSI (US), BSI (UK), AFNOR (France) and DIN (Germany).

The aim is to set up an organization so that its processes produce reliable service. The guidelines require each part of the operation to be systematic, consistent, reliable and show common sense. They use a generic vocabulary that permits any organization's reliability to be verified by an outsider.

Any organization now has the means to show a potential client that it can provide that client with quality service, and any client can now verify in advance whether a potential supplier would be likely to produce reliable products and services. This process of verification in advance has become so useful that it is now an essential underpinning of the development of the global economy, and certification to the standard is becoming a basic management requirement.

#### The Impact of ISO in the Global Market

The International Organization for Standardization, based in Geneva, Switzerland, provided a forum in 1987 for the development of international agreement on the essential elements necessary to be applied in management to guarantee customers quality products and services. Their ISO 9000 standard allows for third-party audit of quality in an organization. With it, both customers and management know if an organization is set up in a way that will foster quality service as its output. If not, it can pinpoint the areas that need to be studied and adjusted.

With ISO now the practical basis for much of world trade, particularly with Europe and increasingly with Japan, our major corporations are rushing to achieve certification. With it, companies are able to manufacture within Canada for sale to world markets. Without it, they are finding themselves locked out of the competition.

#### The Global Market Is Coming To Canada

The public is increasingly demanding products and services that are useful and cost effective. Customers in Canada as well as around the world are starting to take a more serious look at how products are made and services delivered, in order to make sure that the end product works for them.

Customers are starting to require that suppliers meet standards consistently in order to win their loyalty. The supplier's protestations of excellence or effort are no longer convincing to customers; they are requiring conformance to independent standards and certification by independent auditors.

Companies from outside the country are increasingly able to provide customers in Canada with the quality the customers need. Even the smallest companies in Canada are finding the global marketplace begins at their front door. Whether they survive and prosper depends on their ability to demonstrate to customers that their loyalty is earned by quality they can rely on.

#### The Elements of ISO

The ISO standards and guidelines include the elements listed below.

- ISO 9000 Quality Management and Quality Assurance Standards -Guidelines for Selection and Use
- ISO 9001 Model for Quality Assurance in Design/Development, Production, Installation and Servicing
- ISO 9002 Model for Quality Assurance in Production and Installation
- ISO 9003 Model for Quality Assurance in Final Inspection and Test
- ISO 9004 Guidelines for Selection and Use of Standards
- ISO 9004-2 Guidelines for Services

#### More on ISO 9004-2

Canada took an active role in the development of the standard on quality service (ISO 9004-2), which is available from the Canadian Standards Association (CSA) at 613-238-2223.

The ISO guidance standard, ISO 9004-2(1991): Quality Management and Quality System Elements - Part 2: Guidelines for Services, presents quality

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system principles and operational elements, including service performance analysis and improvement. It describes its scope as follows:

This part of ISO 9004 gives guidance for establishing and implementing a quality system within an organization. It is based on the generic principles of internal quality management described in ISO 9004:1987 and provides a comprehensive overview of a quality system specifically for services.

This part of ISO 9004 can be applied in the context of developing a quality system for a newly offered or modified service. It can also be applied directly when implementing a quality system for an existing service. The quality system embraces all the processes needed to provide an effective service, from marketing to delivery, and includes the analysis of service provided to customers.

Primarily, the customer will be the ultimate recipient of the service external to the organization. Frequently though, the customer can be internal within the organization; this is especially so in larger organizations where the customer can be at a subsequent stage in the provisioning process. While this part of ISO 9004 is written principally with respect to external customers, it can also apply to internal customers for overall achievement of the required quality.

#### **ISO** Quality Definitions

Some of the ISO definitions relevant to Total Quality Management (TQM) are as follows:

#### Service

The results generated, by activities at the interface between the supplier and the customer and by supplier internal activities, to meet customer needs.

#### Quality

The totality of services and characteristics of a product or service that bear on its ability to satisfy stated or implied needs.

#### Service delivery

Those supplier activities necessary to provide the service.

#### **Quality policy**

The overall quality intentions and direction of an organization as regards quality, as formally expressed by top management.

#### Quality management

That aspect of the overall management function that determines and implements the quality policy.

#### **Quality system**

The organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

#### The International Organization for Standardization

ISO (The International Organization for Standardization) is a worldwide federation of national standards bodies, at present comprising 91 members, one in each country.

ISO promotes standardization and related activities all over the world, and develops and publishes International Standards. These activities facilitate the exchange of goods and services, and foster mutual cooperation in important spheres of human endeavour -- intellectual, scientific, technological and economic.

The scope of ISO covers standardization in all fields except electrical and electronic engineering standards, which are the responsibility of IEC, the International Electrotechnical Commission. Together, ISO and IEC provide a system for international standardization as a whole --the world's largest non-governmental system at the international level.

A 'member body' of ISO is the national body "most representative of standardization in the country". It follows that only one such body for each country is accepted for membership of ISO.

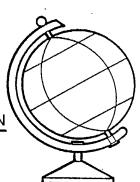
The majority of the ISO member bodies are governmental institutions or organizations incorporated by public law. The remainder have close links with the public administration in their own countries.

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION ORGANIZATION INTERNATIONALE DE NORMALISATION

Case postale 56 Geneva Switzerland Telephone (022) 749 01 11 Telefax +41 22 733 34 30.

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# THE CASE FOR ISO 9000



#### The Case For ISO 9000

#### Why Consider ISO?

The globalization of world trade has brought competition on an international scale to industry. The key to competitiveness now is technology.

ISO is uniquely equipped to help you prosper in this environment. You can find a world of opportunities open to you with the management technology and expertise it can put at your fingertips.

ISO activities can help you to identify upcoming needs and opportunities for Canadian customers and provide you with information essential to the success of your enterprise at home and throughout the world.

The synergy ISO produces, with customers and among staff, brings you cutting-edge results to help you achieve the technological advantage you need to compete and to succeed.

As the world's primary management technology source, you can use ISO to reduce your costs and meet the quality your customers demand.

What is the original impetus for companies undertaking the significant effort of designing and implementing an ISO 9000 quality system?

- Our competitors are either already registered or have plans to be registered with ISO.
- Our customers are requiring compliance to ISO 9000.
- ISO 9000 helps us accelerate the rate of quality improvement.

The Case

#### The Advantages of Using ISO 9000

The ISO system has several advantages for management, as listed below.

- The ISO system is the most widely recognized quality management system in Canada and abroad.
- Since it was adopted as the basis for Europe's ecomomic union in 1992 it has become a prerequisite for contracts with European business. As such, its use gives a common language for dealing with industry and the public, and a common standard for evaluation of the quality of work done by all parties, including the regulators.
- With it, an organization can find new people and train them easily, giving staff portability and the organization access to the experience of industry and others.
- The ISO system allows third-party auditing, which adds to credibility and improves management.
- It is quantifiable and so clarifies and demystifies a sometimes complex subject.
- Because guidelines and training for implementation are publicly available, any organization can evaluate the work of any consultant but is not tied to any specific one.
- Although ISO is a product of international cooperation, much of the expertise is available here in Canada.
- The use of the ISO 9000 system of quality assurance is likely to improve the basis for good relations between industry and the public.

#### What Companies Say About ISO 9000

These seven companies, which are working with or in the process of implementing one of the ISO 9000 management standards for their internal quality-management system, talk about the benefits they see.

# Monsanto













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AT&T operates interstate and international toll networks and portions of the interstate networks. AT&T also owns local on-premise equipment, Western Electric, and Bell Laboratories. AT&T has 316,400 employees.

"The ISO standards, which are recognized world-wide, define the key elements needed in an Quality Management System.

"We have used the standards as a tool to ensure that our Quality Management System is customer-focused, effective and cost-efficient.

"The standards provide a foundation for assuring that we build quality into our products throughout the development life cycle. The results are evident in the world-class quality products that we deliver to our customers.

"Compliance to the ISO 9000 standards has helped us to continue to accelerate our rate of quality and productivity improvement, and has supported our application of Total Quality Management principles throughout our business.

"The ISO 9000 standards are an effective tool for ensuring that we are continuously improving our quality systems and processes so that we consistently meet or exceed our customers' expectations."

#### Lilah Houeye, Quality Assurance Manager, AT&T Network Systems

"Customers have had an excellent reaction. Once you begin working toward certification they see that you are motivated, really making a commitment to their needs, not just giving lip service. They see you are serious about doing business, and that you want to lead the industry.

"We told our customers that we are going after ISO 9002 certification in the service sector, because it ties into the whole TQM effort in the company. It makes you consistently review processes to ensure you are at least meeting, or exceeding, the expectations of your customer."

"It also ties into developing partnerships. What we learn through ISO we can then share with our customers. We try to develop open and honest communication with our customers and it seems to be working very well. We get monthly delivery evaluations from our customers that we review with them, we work together with them to an agreeable resolution on any issues and we make sure we are aligned. When they see responses to their comments it really makes a big impression.

"It has opened up communication with suppliers, because you are both after the same goal - lower production costs, leading to lower end-user costs. By pulling in these standards, it has been a benefit not only to us, but also to our customers and to our customers' customers.

"It gives you a common bond internally. It brings enthusiasm to people."

Karen Oliver, Quality Manager of National Systems Canada, AT&T



AVESTA ABE Ltd.

ABE produces stainless steel fittings used in the pulp and paper industry. The company achieved certification to the ISO 9002 standard in the fall of 1992. There are 39

employees at the Brockville, Ontario plant.

"We feel ISO is the way to go now.

"The smallest of companies are putting in a quality program. There seems to be a chain reaction. Most of our customers have implemented quality programs and prefer to deal with certified companies.

"Our in-house QA program was formalized to comply with ISO and CSA standards. The process took two and one-half years. Since our certification, many of our clients have asked for a copy of our manual and certification number prior to their purchase.

"The ISO standard has helped our processes from order desk to shipping door. It provides written procedures to fall back on, rather than memos or verbal instructions. If anyone has a question, there is a manual to consult. When an explanation is needed, staff know where to find the answer."

Liam Cullen, Production Manager

LPB Poles Inc. manufactures CCA-PEG pressure-treated utility poles. The company is a wholly owned subsidiary of Bell Canada that employs 44 people in Masson, Quebec.

Anything worth striving for requires effort and commitment, and ISO registration is no exception. It starts by putting down on paper the basic elements of your business activities. It includes the methods used to achieve its function, customer specifications, and the documents generated that demonstrate the function occurs consistently. Any company doing a good job would welcome the ISO system. It formalizes and re-enforces your own system and signals your customers that you are serious about your business and the products and services you deliver.

LPB Poles views its ISO accreditation not as an end, but as a beginning, a foundation on which to build a Total Quality Management company.

Any service or manufacturing company has many people performing a variety of functions, and their paths are continually crossing.

"We introduced the CSA system standard in 1989 and added ISO when LPB re-registered in 1992.

"Our customers demanded a high-quality, consistently produced product. We needed to respond to these demands and to build internal communications and understanding along the line and up the line.

"LPB Poles has had a registered quality system for over four years. Time enough to clearly see the benefits to our customers and to our internal production facility. Doing it right the first time, on time, saves time, which in turn saves money.

"The CSA and ISO quality systems put your company on the rails and set the direction and course companies must take in the future. For LPB it is our foundation, and it has allowed us to progress towards a TQM system, involving such elements as a green plan, employee training programs, profit sharing and peer reviews.

"Its beyond me, how these companies successfully function in today's business environment without ISO. Probably a lot of things fall through the cracks and they don't know it. It's not business as usual in this global business environment. There are definite cultural changes taking place and Canadian businesses are going to have to move along with them or lose."

Scott Henry, Vice President of Environment and Quality

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Northern Telecom is based in Mississauga, Ontario, and employs 57,955. The company researches, designs, develops, manufactures, markets, sells, installs, finances and services digital telecommunications switching systems, including central office switching equipment, business communications systems and terminals, equipment cable and plant products, and other products and services on a world-wide basis.

# It's not enough in today's competitive business environment to claim your company offers a quality product or service. You must prove it.

That proof, as many quality experts agree, is the ISO 9000 certification awarded by the International Organization for Standardization. But the company seeking the ISO stamp of approval will face a mountain of work and intense scrutiny from independent quality auditors.

So why would a company bother to apply?

For one thing, ISO certification is recognized in more than 90 countries as a definitive quality standard. Moreover, Northern Telecom's customers are demanding it. One of Northern Telecom's largest customers, BT, formerly British Telecom, will require ISO compliance from all its manufacturing suppliers, beginning in 1993. Customers in Canada and the United States are also jumping on the ISO bandwagon.

Northern Telecom is committed to achieving ISO 9001 certification for all its manufacturing facilities by early 1993. More than half of the company's locations are already registered to the ISO 9000 level.

ISO certification is, however, much more than a bureaucratic paper chase. It's estimated that firms with ISO 9000 certification have, on average, reduced their operating costs by ten per cent through continuous improvement programs.

The ISO standard provides essential business advantages to both customers and suppliers because it:

- provides instant recognition that a quality management system exists in your company
- signals that your company is dedicated to minimizing costs and continuous quality improvement
- instills greater effectiveness and economy in your operations.

A manufacturer seeking ISO certification must be prepared to define - and reveal to customers - their quality management systems. The principle is simple: document what you do; do what you document; and produce the quality of product you say you will.

Intensive examinations are typical during the certification process, which includes a three-day audit involving hundreds of employee interviews. During the audit, employees are quizzed about the processes used in performing their jobs. Their verbal explanations are compared with the documented processes.

"Given our emphasis on Excellence! we are particularly pleased that many of Northern Telecom's facilities have been certified.

"What is ISO 9000? It is not a set of product specifications. Instead, it is a set of quality system standards and guidelines. It serves as an international quality assurance, and says that we deliver quality in everything we do. The ISO 9000 is awarded only after an exacting, external audit of all activities. We expect soon to be a global company with total ISO 9000 status."

#### Keith Powell, Vice-President, Customer Service and Excellence!

"For companies like Northern Telecom, ISO certification offers a competitive advantage that admits us to new global markets and protects existing ones.

"In the future, only those companies that are registered to this standard will be able to do business. In other words, it is more than an option - it is a must."

# Bill Morgan, President of the Transmission Components and Services Organization

"It takes most company locations about nine months to achieve ISO 9000.

"We are now producing a common set of manuals for use worldwide, which can be used as a blueprint for future applications and for maintaining and improving standards.

"There is no question that we are taking an aggressive position on ISO 9000 certifications."

Cleayton Mills, Vice-President, Product Assurance

The Case

Eastman Kodak Company, Kodak Canada's parent, is the world's largest producer of photographic products. Kodak makes amateur, professional, and commercial imaging equipment and supplies, information systems, synthetic textile fibers, plastics and chemicals. Eastman Kodak Company employs 133,200.

"Our motto is, Manufacturing in Canada for the World."

Ronald C. Morrison, President and General Manager of Kodak Canada

"When you are this crazy about quality service, you should be certified.

"ISO 9001 equals certified quality. We are proud to be certified under the ISO 9001 Quality Assurance Standard adopted by the International Organization for Standardization. We're proud of it, because certification gives our customers and us a competitive edge.

"The series of ISO 9000 standards is becoming a defining competitive criteria for advanced companies in Canada and around the world. They are already what amounts to a market requirement for doing business in the European Community.

"ISO certification reduces the need for time-consuming and expensive evaluations of Kodak practices. Customers can rely on the ISO registration stamp, knowing with confidence that the vendor who shows it meets rigid quality standards."

#### Recent advertisement by Kodak Canada

In the photo accompanying the above advertisement, 12 representatives of the 300 staff members of Customer Equipment Service are rejoicing around a sign announcing their recent achievement of ISO 9001 certification.

On March 30, 1993, Kodak Canada published in the Globe and Mail the president's letter of congratulation on the certification of the most recent division:

#### To Kodak Canada Men and Women

Kodak Canada recently reached an important milestone on our journey to world-class excellence. Our Manufacturing and Supply operation was certified to ISO 9002. This gives us cause to celebrate!

Above all, our achievements under the ISO 9000 series are a tribute to all of you whose good work enabled us to earn this accreditation, and to you we want to express our sincere appreciation.

We could not have reached this important goal without your talents, your focus on the task, and your dedication. You've proven once again that Canadians can compete!

Yours sincerely,

Ronald C. Morrison

President and General Manager

Edward S. Jurus

Vice President and General Manager

Manufacturing and Supply

The Case

# Monsanto

Monsanto Canada Inc. was the first chemical company in Canada to achieve accreditation to ISO 9001. Registration was awarded in 1992 to the Lasalle, Quebec plant. The Monsanto group of companies together research, manufacture and market their products and employ 1,400 people across the country.

### "All Canadians, regardless of their jobs, have to get more involved in fostering competitiveness.

"Business in Canada will never be business as usual again. What remains constant is the need to change and improve to ensure a prosperous Canada.

"This registration reflects Monsanto's success in attaining the quality and competitive levels necessary for all Canadian companies to prosper within the business environment today and into the future. We publicly committed to meet stringent ISO standards by the end of 1991. We met that challenge.

"The achievement of the ISO 9001 rating is very significant to our customers. It is a guarantee that Monsanto Canada's manufacturing operation delivers what it promises. It means we can provide products and services anywhere in the world that customers can rely on without having to doublecheck through their own internal quality systems, which saves them time and money."

#### Ian Lennox, President and Chief Executive Officer

"This recognition also allows us, in turn, to help our customers sell more effectively to their customers.

"The Canadian auto-parts industry, for instance, has been working hard to demonstrate the quality of its products to vehicle manufacturers. With one of their key suppliers holding the distinctive ISO 9001, it demonstrates an extra quality step that is impressive to all our customers."

#### Terry Butryn, Business Manager, Automotive

"Obtaining this accreditation ensures that we are able to compete in global export markets."

#### Ron Doyle, Business Manager, Paper Products

"The ISO 9001 is important because people know that we have a quality system in our organization, especially with registration at the highest level of the series."

Guy LaPlante, Vice President, Operations at LaSalle



Mitel Corporation directly and through subsidiaries, designs, develops, manufactures and markets electronic telecommunications products and semiconductor devices including private automatic branch exchanges (PABXs), key telephone systems, public switching systems, datasets, terminals, and other equipment to serve its customer's communications requirements. Research and development activities are conducted primarily at the company's Kanata, Ontario facilities.

The prestigious 9000 quality registration is a source of pride for Mitel. It is also a source of confidence for Mitel customers - they gain the advantage of dealing with an operation independently certified for its Quality Management System. It means being able to count on the continuous progression of superior products and services such a System produces.

ISO 9000 was created to define and establish the vital elements of management systems affecting quality in industry. Widely embraced in Europe, the standards are a growing worldwide influence. The ISO's role in shaping and validating quality levels in business and industry is expected to be a dominant one in the open European Economic Market as well as the rest of the global arena for a long time to come.

Meeting the rigorous standards set by the International Organization for Standardization isn't an event - it's a process. For Mitel, it started years ago, with a corporate commitment to improve management systems as a basis for improving products and services.

In the ISO 9000 series' focus on quality management and customer expectation, Mitel found the highest standard to aspire to in defining the most effective systems and processes for producing products that consistently meet changing customer needs.

From quality design to quality assembly to quality servicing by quality personnel, the discipline of ISO registration raises Mitel's already exceptional performance to unexcelled heights. Mitel is more prepared than ever to systematically build quality into the entire life cycle of the products.

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The Case

#### What Executives Say About ISO and Leadership

These are the comments of a senior executive of a company that was registered to ISO 9001 several years ago. The executive talks about the qualities of character needed for leadership.

#### Sustained change requires personal transformation.

The job of senior executives changes from strategist and technician to behaviour expert. They have to work harder than they have ever worked in their lives.

No turn-around company has a leader who has not undergone a personal transformation. We see everyone as links in a chain that is only as strong as each of its parts. Behaviours are a critical, integral part.

For us, quality is not an option. Sustained improvement depends on individual transformation. People are not the same. They behave differently. The key word is integrity.

Start with the leaders first. Get the leader to announce change, then go out and invent it. Live it every day. The senior people have to be evangelists, and if not, boot them out.

Generally, senior people in a company only tolerate each other. They tend to be clever people each with their own agenda. You are very lucky if you can call anyone a friend.

Here we are each other's coaches; any self-serving behaviour is exposed. We recruit for individual integrity; 50% of screening is for the kind of person they are. We see incompetence as behaviour that is inconsistent with our vision and culture.

We believe all people are good and here for the right reasons. An action is a thing, not a person. We do not change the person, we change the behaviour that is inconsistent with what they are. You have to be responsible for the way people interpret you. You yourself do not change, you become responsible for interpretation.

Our responsibility to each other is to put up a mirror for each other, and show any dandruff flakes. We hear it as constructive criticism, and then carry on. Our job is developing skills and initiatives at the top.

The talent of the leader is to find those who can drive the process. There is a lot of behind-the-scenes work, marrying behaviours and process. You can't take a day off.

For us, empowerment means the leaders set the direction, and we coach and provide the tools to get the outcome. We empower the organization to invent the 'how'. We stop 'hows' that are against the principles of the company.

Integrity includes managing within budgets.

What we teach is ISO; 'how' is as an empowered group of practitioners. Here we operate differently. We treat each other with dignity and we teach that.

#### **What Staff Say About Benefits**

While competition and customer requirements are usually the reason for beginning ISO registration, once they begin, companies find their decision supported by economic benefits, such as cost savings in production and increased revenue from satisfied customers, and by human resource benefits, such as staff empowerment and reduced stress.

These are typical comments a visitor hears about benefits in an ISO registered company.

- ISO 9001 takes the process and analyzes it using brainstorming and flow charts, to ask yourself if there are steps you can cut out: does it save time, does it affect quality? If it saves time and it doesn't affect quality, bingo, you just saved yourself money. You ask yourself about every step. Fitness for purpose means use just what is needed. We need tin, not gold, paper clips.
- We have the highest quality product in the world it is already very good and reliable and we already have an effective quality system in place. But, we know we have to keep improving our product and to accelerate our rate of improvement, and we have to get our costs down and be more cost efficient. We feel the added discipline of ISO 9001 will help us do that. We see ISO 9000 as a way to accelerate our rate of quality and product improvement. ISO 9000 will help us to increase our productivity and to build quality in from the start.
- There is going to be a lot of work at first and people will have to change the way they do things. Once it is all in place and things are running more smoothly, there is less stress, people enjoy their jobs more, they know where to go for information and everyone is well trained; it makes for a healthier, happier work place.
- We find that there is nothing in the ISO 9001 system that you do not need; you have to have all the elements to have an effective quality system. It provides the foundation the essential minimum requirements for an effective quality management system.

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- This makes sure that all the organization can benefit from new good ideas.
- With this ISO 9000 approach, new ideas are first tried out, hard data collected and studied, and then management makes a decision. If the new way is adopted, people are trained and then everyone follows it. In the past, people may have tried out better ways of working, but without this formal approach, the improvement came to just one part of the organization and did not improve the organization as a whole.
- What ISO makes us do is take a close look at how we do things. ISO has forced us to be structured in what we are doing. What it does is help give us a paper trail. Before, we tried to remember what we did last time, and tried to do it the same way, but we had to rely on memory; now it is written down and so we remember exactly what we did. It makes us learn good habits. Once you are ISO registered and you have a procedure management has signed off to, they have to abide by it. Before, we were always trying to meet schedules; now we can say no, we have to meet procedures. Now we have a procedure, and we use it as a crutch to make management set more realistic schedules. Now that they have something they have signed up to, we can make them slow down, so we have a chance to do it right to produce a quality product.
- If you do this it will make your job a lot easier. Everyone will know what everyone else is doing, as far as doing their job. They will have more confidence and a happier work place. There is some grief up front, because management expects us to do it while we do our other workload; managers have to cut some slack.
- ISO was an integration more than an implementation. It gives us recognition of what was already happening here.
- CEOs can relate to it. They visualize action. They can turn the ISO concepts into reality in their mind. TQM is often delegated down the line.
- If your president can't sit behind his desk and know he is not wasting money, I don't think those companies are going to be there in another ten years. It is not that your profits are going to go up immediately, it is saving money.
- After a few years if you ask people in operations if it is a good thing, you get nothing but the same answer. They like it and it saves you money. You don't waste money and you don't waste time.

#### An Example of Work Conditions in an ISO-certified Company

A person working in a certified company discussed the working conditions and the management process from his point of view.

#### How would you change something in your company?

You should go through your chain of command. You start with either your boss or the one who would be affected by it. I would just say that here is something I think we could do better if we did it like this.

#### Have you ever tried that?

I changed the way our test equipment is stockpiled. Before, we kept all the test equipment in the lab in the general area where we were going to use it. It was hard to control and we never knew where anything was.

Now, it is behind one locked door with a sign-out sheet, and someone is always around to sign it out. Now, when someone needs the equipment, they can see on the list who has it and when it is coming back. That has really helped out a lot. I like to know what is going on and where my equipment is at.

#### What happened?

I got fed up with not being able to find my test equipment. On May 5, I sent an E-mail to my boss and then discussed it with him. Everyone mulled it over, and on May 6, I made a formal proposal. He agreed right away.

Just a couple of weeks later, we got everything taken care of. We have moveable walls, so we reshuffled some meeting rooms to get a corner near the lab. My boss was responsible for the area, so he had the authority to do it.

#### How did you find someone to look after it?

Someone volunteered to do it, and it became one of her new jobs, as a lab technician. When we do our performance reviews, you get raises based on the work you do, and when you take on something like that, everyone is grateful, and it helps your review. We do peer group reviews, and so people are willing to pitch in and contribute. Reviews are what decides what percentage raise you get, depending on the number of years you have

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with the company. I also got a brownie point for the idea; it was a big plus that I took a positive action like that.

#### How do these evaluations work?

All the bosses get together by invitation from my boss. He sets up a chart to show what each one of us accomplished during the year, based on quarterly goals, and they sit down at the end of the year to see how well you reached these goals, and what other initiatives you undertook. They rate me on my test plan, whether I understand my project well, and on my interaction with the others.

They put on the chart how we are viewed by everybody on our site. One of the slogans around here is that everyone has a customer. My boss says to me that if you don't have a customer then you do not have a job -- who are you working for, yourself? If you don't have a customer, then you are in trouble, and you look for your job to disappear.

We go out and solicit comments from our customers. Even if they are other employees, they are customers, and it is very important to my boss that I please them.

We go out via E-mail to solicit input from other sites - they are really big on that. My boss contacts everyone I worked with during the year. He makes up a form and sends it to about 100 people. About 40 respond. That is still a good cross-section, and he figures those who do not respond had nothing to say. If you do a good job for someone, they are going to want to reward you, and if you get a lot of people out there hating you, then you are doing something wrong anyway.

It is really a good idea, and I like it, because it helps to give me some focus. There was no resistance to it when it came in. It was a good idea, plus it came down from senior management, so it could be not be resisted. That is how it should be. That is why you have senior management.

#### Allay Fears Of ISO 9000

Communication is vital in setting up an ISO quality management plan. These are typical questions you will face from staff or management, with answers from people at all levels of all sizes of companies.

## I have heard that ISO requires lots of documentation. How much detail do I need to go into?

The process needs to be described in the level of detail necessary to get a quality product. If how people do a certain part of the procedure does not affect the quality of the result, then you do not need to have it in the procedures. We have a lot of discussion to figure out what level of detail we really need.

#### How does ISO 9000 compare to Baldrige?

We see ISO as a foundation, and we are building on that foundation with the Baldrige criteria. Baldrige deals more with customer interface and employee recognition.

#### What was it like to go through the registration audit?

People were a little apprehensive about the first quality audit, but once the interview got underway they were not as worried. The auditors really do use common sense. They asked what you did and how you did it, and asked to see quality records of things. They just ask something and you explain it.

#### I know how to do what I do, so why do I have to write it down?

There might not be more documentation, there may be less. That is not the point. It is organizing it in a rational manner that an outsider could understand.

# Workers are reluctant at first to participate in an ISO 9000 program, because they think it is just another fad program. What gets them motivated?

Staff see programs come and go, and so they are sceptical, but when they see technical publications in their fields full of articles on ISO 9000, they realize that it does affect their area and they realize it is more than just a passing fad.

## People do not believe it is as significant as it is made out to be. What changes their mind?

People see the size of the contracts being made with Europe and they want a piece of it. They realize then they need registration for their own economic survival.

# Without real commitment by managers, staff feel production will once again take precedence over quality. Staff have worked hard on other quality programs and seen them lost to management's pressure for production. What makes this any different?

The difference with an ISO 9000 program is that this is global and international. Everyone is spending a lot of energy and money, including major international corporations. They see it referred to in every technical journal. To keep up the company's registration, managers have to stay committed. With the competition involved, they will.

### Won't this just create tons of additional paperwork and put staff into a headlock?

As an ISO 9000 program settles into place, staff come to really appreciate it. They like being able to have reports on hand easily and equipment in calibration, and so on. It is a lot of work to get started, but having a well-organized system that makes sense saves a lot of work in the long run.

#### What if people feel they are already efficient?

They may be doing things right, but they are not organized as well as they could be. The further ISO gets implemented, the more people see it is a

good way to do things and that it is there to help them and not to hinder them.

#### How do you get started?

The decision to adopt ISO 9000 has to come from the head of the organization.

#### It takes a commitment from everybody. How do you develop that?

Once they get the system in they are going to enjoy it, knowing all the equipment is in its place and the reports on hand, and that all the people they deal with are well trained. They also appreciate that it makes management take a more realistic look at project schedules and resources. There is no more just 'making do' or just doing the best you can. You do not have to use shoddy or out-of-date equipment. There are a lot of advantages to be had and people see that.

#### Does all the testing slow down the process?

You have to build the time into the process. If quality is indeed your aim, then the fact that it slows down the process is not as important as getting the thing right. When you get it right, you save back all the time and more in not having complaints, corrections and re-work.

# When you inspect and audit each other with the internal-audit program, how do you stay on good terms with people?

We try to stay away from finger pointing. We all realize people will make mistakes, stuff happens, and part of our big policy here is we are one team, and so if someone has a problem, we all have a problem. Although I am in quality control, I am also in the design community here.

#### How does ISO affect empowerment?

The guys in the plant know what I know. They know how to find out and how to make decisions. We tell them it is fine to check with people if they want - that is what a team is for - but if no one is around, then just make the decisions yourself; the only thing you can do is make a mistake, and if you do, then we can easily track it down and correct it.

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#### Some people are afraid of ISO. Is that fear justified?

If you are doing a good job you should not be afraid of ISO. If you are cutting corners, or are a company that does not do a good honest job, you should be afraid of ISO.

#### How does ISO improve a company?

When a company begins an ISO program, people often say that it is just a matter of writing down what they do. Once they start writing it down, however, they start to think about what they are doing, and develop ways of doing it better. Putting it into writing makes people sit down and talk things out, and that always helps. In the end you will find ways to improve, and things are only going to get better and better. The internal-audit program institutionalizes this process and makes continuous improvement possible.

#### Does ISO apply to small companies?

I think it is easier for them. In our plant, the process is handled by just a few people, so it is easy to document and easy to change.

# 3 ISO 9001 QUALITY SYSTEM REQUIREMENTS



# **ISO 9001 Quality System Requirements**

### What You Will Find In This Section

There are 20 elements covered under ISO 9001. This section will give you an introduction to each one of them. For each element there will be a description of the basic idea, along with some reports of practical experience with that element in practice, and in some cases a series of questions to act as a checklist. The quotes are from people who work in ISO-registered companies, who can give you a sense in their own words of what ISO feels like.

# The 20 Quality-system Requirements

The standard, ISO 9001(1987): Quality systems - Model for quality assurance in design/development, production, installation and servicing, identifies 20 areas an organization must address in its quality manual and the standard for each necessary to achieve registration.

- 1. Management Responsibility
- 2. Quality System
- 3. Contract Review
- 4. Design Control
- 5. Document Control
- 6. Purchasing
- 7. Purchaser-supplied Product
- 8. Product Identification and Traceability
- 9. Process Control
- Inspection and Testing
- 11. Inspection, Measuring and Test Equipment
- 12. Inspection and Test Status
- 13. Control of Non-conforming Product
- 14. Corrective Action
- 15. Handling, Storage, Packaging and Delivery
- 16. Quality Records
- 17. Internal Quality Audits
- 18. Training
- 19. Servicing
- 20. Statistical Techniques.

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### 1. MANAGEMENT RESPONSIBILITY

Managers committed to making sense from the client's viewpoint, procedures that are able to produce the agreed-on service, and a way of adjusting the organization to real-life results: these are the prerequisites for quality service. These first steps are the responsibility of the managers.

In fact, quality assurance in any organization begins with management, and much of the responsibility remains with them. Research has shown that up to 80% of errors and failures are attributable not to errors by staff but to errors in the way the work was designed or resources allocated, which are both areas of management responsibility.

Managers establish the service benchmarks, set up the quality assurance procedures, and make sure they are followed. Managers must assign clear responsibility to make sure the quality-assurance system is working, and undertake regular reviews of whether the work process accomplishs the organizations goals. If they do not, managers are responsible for ensuring the organization adapts.

The service benchmarks are given life by the managers, who state by their actions the level of service they intend the organization to provide. To foster better service at every stage of service delivery by the organization, managers need to ensure the statement they make is well thought-out and productive, and that it is understood by everyone in the organization.

## There are four main areas of management responsibility:

# The policy on quality

The policy need not be elaborate, but it should be definite. It should state in measurable terms what needs to be done and to what standard.

# The quality system set up to verify it, including plans and manual

The plan and manual flow out from this policy and describe it in practical terms.

# The organization set up to achieve quality

The key to the organizational work is to give the person responsible for quality the authority and organizational freedom to initiate action to prevent problems, identify and record problems, initiate solutions, verify they are implemented, and stop production until requirements are met. In practical terms this means the quality person in the organization must be fairly senior and report directly to the management team.

## The review by management of the quality system

Reviewing the quality system has three purposes:

to ensure it meets the objectives of the system to review the results of the audit programs, and

to verify the suitability of the program given changes in general world conditions.

- When the boss signs off on the policy, it helps a lot.
- We defined and documented our work on a process basis; for example we looked at design, coding and testing. Each process has an owner, who is responsible for managing the process. Many people in the organization implement the process. Even though they report functionally to someone else, they provide feedback to the process owner that is used in making process improvements.
- We place a strong emphasis on ensuring that roles and responsibilities are well-defined and communicated. Without clear responsibilities and authorities you could get a different story from different managers as to who does what. Who is responsible for ensuring a quality product is produced, and what are the responsibilities? If there isn't a quality system procedure and if it isn't implemented, there could be different perceptions as to who is responsible for what, and if it is not clear and not defined then you end up with quality issues. There should be regular management reviews of the system to ensure its application at every level. Bottom line: establish objectives, a method for achieving them and regular reviews for possible improvements. The boss has to authorize people to do what has to be done to get the system going; there are changes to be made, and people will have to have the authority to make those changes.
- ISO helps keep managers on track. The system requires that annually certain elements have to be covered, and therefore managers have to be familiar with these elements. Managers have to sign off on the minutes. The outside auditors check that the minutes cover all the elements.
- Being responsible for the quality system means a manager needs to have a reasonable idea of what is going on and how it is done.

## 2. QUALITY SYSTEM

Each part of the quality policy needs to be backed up by a plan on how to achieve it. The organization sets up a system to ensure the output of the organization meets the requirements it establishes. This includes a quality plan for each objective, and a quality manual.

Every staff person should know what they are doing, why they are doing it and the part they play in the quality of the ultimate product.

The plan and manual include the identifying of any controls that might be needed, what needs to be measured and how, and the standards of acceptability.

## Questions

Is the managers' commitment to quality service known and understood by all staff?

Is the Quality Service Statement applied by staff to their areas?

Is it put into practice by staff in any of their activities that affect service to clients?

Do staff understand how their work affects the service the client ultimately receives?

How do you assure yourself that clients receive the level of service they expect?

During your review, do you ask yourself whether your operations are organized in such a way that you could reasonably expect to meet your goals?

Have you assigned clear responsibility for ensuring clients receive quality service?

Do you know the training needs for each job?

Do you have a way of knowing whether staff have had the training they need for their job?

Do you have a way of knowing that any particular job is done only by trained people?

What do you do with a service result that does not meet requirements (policy on non-conforming service)?

How do you make sure mistakes do not happen again (policy on corrective action)?

### Comments

- The Quality Statement should be visible and people know what it is. We have a mission statement, and we see it everywhere. There are posters around, special memos from the president, and even a special lunch to celebrate registration.
- Managers give you the time to perform the duties associated with it. They have to make time for you to do it that is a commitment. They have to give you the tools and resources to do it.
- Another thing is actually following the documentation. Our quality statement includes, "We do what we say we do."
- We have set levels of quality for each stage of the production process. The product has to meet all the requirements before going on to the next stage. We have owners for all of these stages and clear responsibility for moving the product on to the next phase of development.

Setting up a quality system makes you look at the flow of work. We eliminated a lot of paper. The fact of getting ISO leads to a process redesign and to streamlining of the work. When you put it in place there is a lot of mental work to find a 'common comfortable solution'. It takes a lot of dialogue to put it into place. You have to be aware of how things are done and have a good dialogue with everyone.

To make sure the system does not fall apart when individuals go on holidays, we put only their position titles, not their names, into the procedures manual.

These guidelines are in the System Quality Manual, which is general policy statements and principles. The Procedures Manual goes into detail on procedures and includes an index of the area quality manuals.

Here is how our manual system works. There is one manual for each product line, called an Area Quality Manual (AQM), plus one for each service line that covers all product lines. Examples of service lines are environmental health, maintenance, quality assurance, business and commercial, new products, purchasing logistics and human resources, including training. We found that the service lines are 80% to 90% of the work. The Area Quality Manuals include the policy plus the outline of the procedure.

To set up the manual system, we first told people we wanted certain specific areas addressed and that they were to fill in the blanks. We asked them generally what they would like to see controlled to make sure the end product was good. Some were already in place, and in some areas there were gaps. We allocated responsibility to those who logically should have control. We provided them with the rules and the issues, and then gave them the System Manual and the

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Area Quality Manual for their product line. With this preparation and these materials in hand, they wrote the procedures for their specific area. Once all agreed on what they wrote, we told them that it was their official manual, and that they had the responsibility for it. Once this general manual was completed, we gave them blank sheets and asked them to fill in what areas they were responsible for. We let them have the option of identifying their own areas. We then gave them an organization chart for each product group, and a rundown of the responsibilities of each position.

The approval list:

The System Manual is signed by the president, and the quality board sets up the list of approvers.

Each Area Quality Manual (AQM) shows the name of the person who has the authority for each procedure, along with his sample signature, signed by the official approvers listed in the System Manual.

For example, in AQM006, procedures 002 to 004 are assigned to a particular named person. He has the final authority on these procedures and must sign off on any changes.

There is a list of controlled copies of each manual.

There is a revision list of any revision owned by this manual. Any change has to be signed off by the owner. He identifies the departments affected and sends a copy to each. They then put it in a special section at the back of their manual.

The Work Instructions include everything people work by, signed, dated and logged.

Now each product-service director reports on where the reliability graph is going and on the plans to make it better. On any service call certain things have to be done and they are audited against that. People in the field understand what is expected of them, the way they have to do it and the time it has to be done in. They know the processes are being monitored, not only to see they are being done, but also to improve them. They have opportunities to affect procedures. Workers have a Non-Conformance Report they use to report on problems such as late or missing equipment. The managers go back and identify what went awry.

The Non-Conformance Reports from us in the field go high up into the hierarchy and the managers have to formally read them and sign them. Because the reports go to so many people, managers have to take them seriously. The internal audit program helps make sure that something is done to fix the problem. The person who first puts in the non-conformance report hears back what was done.

Management has a quality-service review meeting with a fixed agenda of a number of issues that are requirements of the ISO standard. Every Non-Conformance Report over four weeks old and not answered is reviewed. We are now moving to make it a business review, to show the state of the business each month and tie reliability and opportunities to manpower requirements. Once a month we meet to see how to make the business better. At the meeting we cover outstanding non-conformances, an audit on corrective action, reliability measures, manpower requirements, and setting up teams to take on major projects - usually from significant non-conformances in a particular area.

We set general objectives that are ongoing, and then specific objectives. A sample general objective would be that material is to be controlled, maintained and accounted for at all times. A sample specific objective within that for a specific group would be to work with engineering to understand how to make the software work better. We review progress monthly in their monthly report. Then annually we review to see how well it was done. There are no surprises in anyone's performance appraisal. It is a question of getting together and discussing issues.

### 3. CONTRACT REVIEW

Agree with the client on what can be done and assume the accountability for getting it done.

The basis of a good contract is agreement on the client's requirements and the limits of your own resources. There should be a mutual understanding of what is to be accomplished by the service, and what the criteria will be for evaluating that service. There also needs to be a standard, formal means for the client to change the contract.

Good contracts cover the mandate of the service, the ability of the organization to meet it, and the criteria for evaluation.

Contracts are necessary with outside clients, but can also be undertaken within an organization.

# Questions

Do you have a complete report on the client's needs?

Does the client agree with it?

Is the underlying policy research and analysis available?

Is there an accurate description of what the organization will be accountable for doing?

How do you know you have the resources to fulfil the contract?

Are any limits to your mandate imposed by legislation or regulation fully described?

Are your clients aware of any limits to your ability to fulfil your mandate? Do you agree on the criteria by which your service will be evaluated? Have you agreed with the client on a means to change the Service Brief?

### **Comments**

Contentious issues have to be resolved before we take an order. On the phone the order person has to know:

if we have the inventory
if we can meet the deliver dates
any special loading requirements
whether they need a certificate of analysis

what special specifications we need to meet any special billing or invoicing.

For any areas unresolved the order person must contact sales, scheduling, transport and the laboratory or other areas to get confirmations from each and coordinate the responses. The order person logs these actions into an entry sheet. That sheet is logged with the order to see what was decided and who was to do what if necessary. Included in the notes is:

out of stock material what was substituted when the delivery left, so the client could be ready the name of the sales rep any new information for the client profile.

All this must be in place before the order is completed.

The order person then calls back the purchaser once all is resolved internally and makes a commitment to the purchaser. We record all exceptions. The order person coordinates internal agreement. Anything permanent is logged into the system.

All of this information goes on to the bill of lading, which goes through the system, so the laboratory, for example, can prepare the tests needed.

- We consider a verbal commitment a contract. We make sure we find out what the clients need and that we can deliver it before the order person accepts the order. It is the order person who coordinates the internal response to the client's special requests.
- Contract review was not done before effectively do we have the resources, training, stocking, and everything in place to do that job. Without that, it might cost more, or affect the service to other customers. ISO says you can't do that. We started to look at things differently.

### 4. DESIGN CONTROL

Doing it right the first time requires investing time in thinking about the way you do things. The Design process produces solutions to meet the accountability negotiated with the clients during the contracting process. Those in charge of designing match the requirements of the contract with the capacities of the organization.

Give the design job to people who have all the training and resources they need to do it well. Before they sit down, the requirements for the design should be clearly defined.

Keep the design flexible but dependable. For the service to be well designed, each element of it must be designed only by staff trained in that field. They should be sure to identify all the factors that are essential to it working properly.

Once the design is completed, the independent advisers verify whether it is able to meet the requirements of the service contract. Assign only people who are competent in the area to verify the design. They verify carefully by tests, reviews, investigating alternatives and comparing the design to existing proven designs. In particular, they make sure it meets the design requirements, that it meets regulatory requirements, and that the designers have clearly identified what the main characteristics are that are essential to it working.

Once established, the design is changed only by trained staff following a process previously agreed upon. Managers are not able to break the rules in response to one-time pressures, but they are encouraged to adapt the rules in accordance with client feedback, as analyzed under Program Review and Evaluation. This frees managers from fire-fighting and gives them time for getting to know the clients' needs in depth and ensuring the organization meets them.

# Questions

Do you ensure that comments gathered by Marketing and Program Review and Evaluation have been incorporated into the design of the service?

Does the service meet the accountability of the Service Brief?

Has a third party reviewed the design of the service, with the power of ensuring the Design meets the accountability of the Service Brief?

Can the service as it is designed be carried out with the resources at hand? Can the service be carried out within the limitations of regulation and other policies?

Is there a standard way for changing the design of the service?

Is there a way to ensure only trained and qualified staff are involved in changing the design?

Are managers effectively prevented from changing the rules in response to pressures from individual clients?

# **Service Delivery Specifications**

The Service Delivery Specifications are the basic requirements for the way the service is delivered. The work includes identifying the essential characteristics of the service that the client sees as value. For each of these, there needs to be a definite standard of performance. Also required is a statement of what resources, people, equipment and facilities, are needed to meet these standards. Once completed, internal advisers who are independent of the area verify the completed delivery procedures to see they are able to meet the requirements of the Service Brief. The design of the service should meet the requirements established by Marketing and be adjusted to real-life experience during service delivery.

# Questions

Have you identified the characteristics of the service that are essential to your accountability in the Service Brief? Examples of such characteristics might be accessibility, courtesy, completeness, response times or accuracy.

Does your policy clearly specify the service standards for each?

Are these characteristics those identified by Marketing as essential to the clients' perception of value in your service?

Do you define the standard of acceptability for each characteristic in practical terms, such as the client would see them?

Have you identified resource requirements, including the type and quality of equipment and resources?

Have you identified the number and skills of personnel required?

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Have your specifications been compared independently with the Service Brief?

### **Control Procedures**

Design a way to ensure the service meets the accountability.

The Control Procedures are the steps the organization takes to ensure that the service as designed is delivered reliably to clients. As an integral part of the design of the service, set up the means to know whether the service meets the requirements of the Service Brief, and what to do if they do not.

## Questions

How do you identify the key activities that help you meet the program objectives?

How do you choose performance indicators for the key objectives? How do you measure and evaluate the performance indicators? What do you do to ensure that the key activities take place How do you know your control mechanisms will be effective?

- For me, ISO means we ensure we have a support network in place to back up new products. We have a written service implementation plan in advance of a new product getting out on to the street, to make sure we have the parts, trained people and tools to support any new product. Today, with ISO, it just doesn't happen that products are out without support. Before a product is delivered, when it is on order, the equipment logistics group notifies the product service directors that a service implementation is now in place. Every month we meet with Sales to project for 18 months, so we know what is coming out 12 months from now. If anything slips through the cracks we have a gate to ensure everything is in place before a product ships out. We didn't have that before.
- We have to supply our customer with a product he can install quickly and easily, and it has to work the first time. There is very little room to have to go back a second time. Every test stage is a non value-added activity. With a perfect design we should be able to produce without testing. The outcome is inevitable if the process is correct.

### 5. DOCUMENT CONTROL

Any quality system relies on staff being aware of what the correct policy is and what the current version of it is. The idea is to ensure that relevant documents are readily available to all who need to use them, and that obsolete documents are removed promptly. The idea seems simple, but to implement it takes some thought and methodical practice.

### **Comments**

- I keep documents in my desk so they are handy, but documents can change and get updated. In our case there can be one change a week to a document. There is always something going on. If the boss comes and says we are using this new document instead of what you worked from, all that work is just dead time.
- When a new revision comes out make sure to contact everyone who uses that document. Make a point of going around and collecting the old version and passing out the new one. Make sure the new version goes on the bulletin board where people can see it. Put up a note with it to say you need this new document and that we will no longer be accepting the old revision. The more you have on-line the better.
- Controlling documents is a major place to increase efficiency. If you take any document you will know immediately if it is the latest update. All originals, such as blueprints, are in the central file. Now we decide who needs the latest copy and who does not. We stamp 'uncontrolled' on copies. If a person needs the latest version they go to the central file. There is an added sense of security you know you have the latest version.
- It is now clear what the changes are and where to file them. The updates are clear. We always had operating procedures, but no one took notice of them until now.
- It makes work easier when everything is in place. As a chemical-solution preparer, we used to memorize procedures. Prior to ISO, no one updated them that often. Then with ISO it went from informal to formal. Now we have to read the procedure, and look to see it is the latest. We must have the most recent procedure on hand and not two versions. It doesn't eliminate variation totally, but it takes away the informal thing and one person being better at it than another. Now we can all make the same chemical solution and get the same assay results.

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Requirements

### 6. PURCHASING

What comes in affects what goes out. In many cases the quality of the finished product depends on the quality of the raw materials. Problems in the final product might be due to problems in what was purchased.

ISO requires you to check material as it comes in. Input from other organizations that is required for output should be checked to see it meets the standards that have been identified for it. Clearly specify what is needed in detail, and verify that what you receive is what you asked for.

First decide and specify what is needed. How much detail? It should be relative to the possible risk.

Check to see it meets these specifications. A habit of keeping track of what the quality was of what came in will make it easy to find the root cause of any future problem.

### Comments

- We used component parts that were good quality. Supplier development was a big part. ISO ensures that raw material is sound. Our suppliers had to be brought in. Our equipment is only as good as what you put into it. If we wanted good product we needed good suppliers as well.
- Today we are down to two or three main suppliers. We have a commitment to them to give them a longer look and longer-term contracts. We have a certification process that takes up to 18 months. It is a formal process with a plaque. What we have achieved is weekly delivery of product and having it delivered to the shop floor at point of use, with 80% going into the stock room with no incoming inspection whatsoever. We have reduced storage time from four to five months to one week. Right on the purchase order it says to deliver to workstation such and such. We flag it on entry and deliver it to point of use. The supplier has undertaken responsibility to ensure quality is 100% on arrival. Ours is just a continuation of the quality process from raw material to the customer. We understand what the supplier needs and he knows what we need and it is just one big manufacturing line.

Originally we were able to have just the 9003 designation. That meant we did not have to keep records on all materials we used. We had a check list to identify how critical the material was, and if there were not enough checks it was not vital to the end product, and we did not have to check it. For vital things we had to check that each lot of the stock was right.

The new ruling from ISO is that if the product goes out the front door any different than it came in, you have to have ISO 9002. That means you have to check the raw materials. If your business is just washing tanker trucks, you can have 9003 and you don't need to test your raw materials.

- Now, we will have to have a consistent system to measure and test that inbound materials meet and surpass the standards. We purchase now according to international formulary standards, but we are now going to have to document and test against the standard.
- Have purchasing requirements very clearly spelled out. The way a raw material is purchased makes all the difference in the world. If some material you purchased causes some problem with your product, and you have not prepared the purchasing papers properly you have no legal recourse. You won't get a cent unless you have properly prepared the documentation.

With certain defects the customer will find out there is a problem once the product is in use in the field. In most products a built-in defect doesn't come to light immediately, it takes years. Unless it is specified in your contract that your supplier has insurance against defects, if there is a problem and you have to sue, he may have no money. ISO makes sure you have all these issues included in your contract, so you can protect yourself and your customer down the line.

That is why we are able to say we will guarantee our product for 30 years. We have everything checked off and we have the ability to fix it. ISO has a system of matching things before they go for signature. When a contract goes to final signature, the person in charge can feel confident.

Everyone is also made aware when we make a new bid, and everyone can comment, including the operations people. If you win you know exactly what percentage profit you will make, because your environment and plant people have all signed off on what is required and how much it will cost, including the effect of special considerations. You don't have any mistakes.

### 7. PURCHASER-SUPPLIED PRODUCT

A client who contracts for a product or service sometimes supplies some of what is used to make the final result - anything from raw materials to statistics or analysis. This situation is called 'purchaser-supplied product' in ISO terminology, and it calls for particular attention.

Take the example of a supplier-client relationship inside an organization. In this example, the client wants some figures to be entered into a database, and brings them in hand written on a piece of paper. The client wants it done correctly, and completed right away.

What to do? There are four steps:

identify what is important to the client

identify how what the client brings could affect the quality

set standards for it

ensure it meets them.

In this case, the client wants speed and accuracy. Speed is affected by the quality of the handwriting, and the accuracy can not be any better than the original. In a well-functioning organization, standards for these characteristics would be agreed to in advance and probably clearly displayed.

At the point of service, the operator would go over the notes with the client, set a time estimate based on how clear the writing was, and promise accuracy in relation to what was in the notes, and not beyond.

In a large-scale operation, there would likely be a formal acceptance inspection of the notes, and the client would sign off against it. There would be a rule that operators would not work on anything that was not signed off, and the supervisor would check regularly that everyone followed the rules.

What does management do to help build quality? They would ask the question, how do you make sure that the clients know how what they do affects quality and that we do not take on responsibility for what we cannot control? Managers would also make sure there were systems in place to let the clients know the procedure in advance and to hear whether they were satisfied with it. If they were not, they would see that the organization negotiated with the clients and made changes with them that worked for both parties.

Under this system, both staff and clients are better off. The staff get the credit for what they can control, but are not frustrated or struggling with fear of bad marks for what they cannot control. The clients are happier too, because they know in advance what to expect and how they can help make a better product. Both staff and clients feel they are working together on the same team instead of as adversaries.

If things do go wrong, this system helps find the cause and to change it easily.

### Comments

- For example, a company that makes modems has us install them in our product and sell them back to them. We have to make sure the modem has the proper FCC 15 and 68, UL and CSA safety stickers, as well as meet some other tests, in order to qualify it for our use.
- When a client supplies parts to us, we do not use anything we do not first qualify. We demand second source in almost everything they do. We give it to our parts people to check. We have to ensure those parts meet all our own specifications, before we include them into our design, and that can be an expensive process.
- It doesn't often happen that a customer supplies us with the raw material, considering the type of work we do in this small company. However, we have thought through a system to ensure any such products don't get confused with our own units. We have on hand forms that people would sign off on, and a procedure to identify what to do if it turned out that there was a defect in what they supplied.

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Requirements

# 8. PRODUCT IDENTIFICATION AND TRACEABILITY

The process of developing the product or service should be laid out clearly. Then, during production, the developing product should be identifiable in terms of these specifications. The purpose is to be able to locate the origin of defects, if they should appear later.

In the development of a product or service, you should know what stages it will have to go through. In process, you should be able to identify what stage it is in, who has worked on it, and where it is going.

Why go to this effort? You can verify at any point that the product is correct so far and fix it if it is not, before the problem leads to others. Without this, you would have to rely on checking for quality in the finished product. 'After-the-fact' inspection often misses hidden factors that show up only in the client's hands. The result would be dissatisfied customers, costly rework and repair.

If a mistake does happen, careful attention to product identification and traceability lets you find out what went wrong and ensure it does not happen again. For example, if the problem was connected to something purchased from a supplier, good notes would enable you to trace the full effects of their poor product. You could also trace where else that defective product was used in your operation, and hopefully catch any possible errors before the client is affected.

- If there is a defect, you can go back to the raw materials to find the defect. You can identify where or at what point in time the problem occurred. For example, you can trace back to the water or the concentrate, and since you can find where each raw material was added, you can track down and correct everything that problem batch might have affected.
- For one area, we might have a frequency of testing of one sample for every fifth batch. The production people write down who took the sample, the time, date, the lot number, how much was taken, and what information was logged on to the sample bottle. In the laboratory, they mark down how it was logged, where it was stored and how it was tested. The delivery people specify how to lay it aside and how to keep it from being mixed up with other batches.

For each of the work orders there is a travelling document. It is an operator's check list. The operator checks the first piece, signs and dates the document, and does a spot check of 15 to 30 minutes. The pieces are hard stamped to maintain the traceability.

### 9. PROCESS CONTROL

Set up a way to deliver the service so that it meets the requirements of the design. Describe each part of the service in written procedures that break down the tasks into understandable parts. Give staff the training they need to be able to perform these tasks and to understand their importance for meeting the organization's contractual obligations to the client. Managers make sure no one does the work who is not trained for it. Review the training regularly to see it covers everything, but does not take more time or resources than is needed to get results.

Together, these steps form the quality plan of an organization. The quality plan should clearly identify those production processes that could affect the quality of the output, and ensure that these processes are clearly described and that they take place under controlled conditions. Make sure you are not working hard on something that does not matter and ignoring what clients really want. When a quality plan for an organization is complete, all relevant processes will receive attention to the extent that they affect the suitability of the resulting product or service for the ultimate client.

### Comments

- The main thing we say is, if you do not have the process documented how are you going to be able to improve it? If something goes wrong, how do you make sure it is not going to happen again?
- Many of our processes have large numbers of people working on them, and so these processes need to be documented because that is the only way large numbers of people can follow them consistently.

The process owners are responsible for the process, and that includes responsibility for continually doing process improvements; they have metrics and they collect data, analyze it, identify areas of improvement, and do root cause analysis.

Process metrics are well defined. The process owners collect data from process implementers, analyze it, identify root causes of any problems which have arisen and make any necessary process improvements. We may have hundreds of people doing design, but the process owners are in a position to see large trends, and make major improvements.

- If you know the rules of the game it makes it a lot easier to play. You can't have people going in there and shooting from the hip and making up rules as they go along.
  - When you write down the procedures you follow, you are forced to think about them and you can see where you can save yourself time and steps. With this there are documented procedures and a systematic way of doing things time after time. After all, the guy next to you can't read your mind. Teamwork is really stressed under ISO, but teamwork happens when everyone knows what everyone else is doing and what they are going to do next. Everyone wants to save time and be more efficient, and with this you can do that, by sending people what they need before they have to ask for it. It all makes for a well-oiled machine, and feels like being on a hockey team that has been practicing for years.
- All manufacturing processes adhere to a Standard Operating Procedure (SOP).

  All changes are controlled by a Limited Manufacturing Procedure (LMP).

  There can be no changes without logging and signing off. The SOP describes the standard procedure and where they are located, so auditors can find them.
- Those who write the documents are those who are closest to the job. They should be working documents, not reference documents.
- Keep in mind when the system is being developed, that procedures must be auditable. We look to see a record, a form, a department, a filing cabinet. The item must be measurable. That way we can assess effectiveness.
- We don't put people into boxes.
- ISO shows you have a quality control system in place, and quality control down the line from raw material to the end product. It does not guarantee zero defects, it guarantees that standards are going to be met.
- If you reduce screw-ups you are going to put more money in your pocket. We didn't want to ship twice or send defective product to the field. Our customers loved us before as a service organization, but ISO gives us a comprehensive framework to give the same or better service for less cost.
- Every rep has a procedure with everything you need to know about the job. A year and a half ago we didn't. Now everyone is doing the same thing. They could take me and put me in Newfoundland and I could go. The parts are the same, and I would find everything I needed in the trunk of the car. Everything works the same, everywhere. If anyone has a question it is all there in the manual. Each procedure has an authorized signature, so we know who to go to.
- Remove any stage that does not add value.

### 10. INSPECTION AND TESTING

There are three stages at which a product needs to be tested: when input arrives from other organizations, during production itself, and then again before the final result is released to the client.

Before you use it, test anything that comes in that will be used in your product to see it meets standards. Then, during your production process, make sure the quality plan is followed and that the process is monitored and controlled as required. Finally, ensure that no product is released until it meets requirements, and that any product that does not meet requirements is clearly marked.

Keep accurate data on service provided, at the point of interaction between staff and clients. Measure the key factors that affect the client's perception of the service. The hard data gathered here complements the evaluations by clients and staff in developing a complete picture of how well the service is delivered in relation to contract.

Listen to clients and their opinions. The clients' evaluations tell the organization how well the clients think the organization met the service agreement written in the contract.

Set up effective means to get a complete picture of how the client sees the service, in relation to what the organization contracted to provide. Also gather information on any changes in the needs or expectations of the clients. The summary of the clients' evaluation is generally made available to the clients. Clients should be aware that their comments will be used to change the service, where warranted, and the process by which this would happen.

The essential idea is that there should be consultation with the clients on how well what the organization sets in place works to meet their needs. This consultation takes place against a background of both the client and the organization sharing an agreed-on understanding of the client's needs and upon the agreed-on mandate of the organization, including any limits to its resources or to its authority under law or regulation.

Make sure staff's comments on the service, and on how they think clients are reacting to the service, are sought out and used in the evaluation of the service.

The organization combines the evaluations of staff and clients with the results of other performance measures, to establish how well it is meeting the contracted obligations. This information is expressed as suggestions

for improvement in the areas of Marketing, Design and Service Delivery. Distinguish between comments that say you did not meet your agreement, and comments that show that the needs or expectations of the clients have changed.

Be sure the cost of inspection and testing is not greater than the benefit.

### Comments

- In our organization there is a gate process, and if a product doesn't pass testing here it does not go on to the next stage.
- Before, we never measured how many times we paged a rep and he didn't get it. If he didn't get it, it meant the customer didn't get service or needed to call back.
- Product management finds out what the customer needs, and then design does it. Before we had several stages: prototype, technical trial, field trial and even testing at the customer site. ISO gives R&D a discipline. Now we have a two-stage cycle: prototype to customer site. Our end objective is to go from design to customer and eliminate the redundant testing stages. In-house manufacturing lead time used to take five weeks from start to finish and now we can do it in two to three days. We had to inspect before every stage to be sure it was good. That was because quality rested with the quality director rather than everyone in the line.
- There were 48 people in Quality five years ago, and now there are seven. And our quality is better. Inspectors add no value; they impede the flow. They were however catching problems. Today the workers take the responsibility. The Quality people are in an audit role and support by feedback to the other areas and maintain contact with the customer.

Before, we would set up extra time for fixing. We put the best people on re-work and anything that went awry went to them. We paid inspectors more than operators. Looking back, it was a joke. We were throwing money out the window.

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Requirements

## 11. INSPECTION, MEASURING AND TEST EQUIPMENT

Every stage of inspection, measurement and testing uses some kind of equipment or process, such as surveys, interviews or other instruments.

Make sure the measuring instruments and tools you use to see whether you are on track are looked at regularly.

For inspection to work, the tools have to be accurate. A few tips:

identify what aspect of the equipment needs to be checked and how to best do it, and work out what the acceptable range of error should be in the calibration

be sure that your tests give you the accuracy you need in the results, and if not, change what you do

be sure to do the checks on a predetermined basis and to keep records of the results.

### **Comments**

- At our company, I know right away that everything in the equipment room is calibrated, and if anything is not in the room I check the log book and see where it is and when it will be back. If anyone wants to know where I am and what I am doing, it is all in the book.
- What ISO does for us? People more likely now to use test equipment and we know where the equipment is. It is a very good paper trail of where everything is and what you have done.

We had things pretty well set before, but we use all kinds of calibration, and it helps us get our test equipment up to snuff and get a good system in place. We have a lot of equipment coming into and out of the lab, and now we have on hand what we need to know: the release level, who did the testing, when it was done, and what release of software we had in it. It has helped us to achieve all our test plans and test reports in a very orderly manner. It is now all available on disk at the secretary's desk.

- Regarding calibration, we can ensure no equipment leaves here without all the testing being done and a sign off from the customer. That protects us if the equipment fails later. We can establish it happened outside of our plant or that it met requirements set up by the client.
- ISO says to identify critical elements in the process and make sure the instruments we use to measure them are calibrated. Now we can demonstrate

- that that has been done. As a result, we no longer need to test every product, because we know the process is under control.
- ISO forces you to develop a matrix of calibration. You know it is being done.

  There are stickers right on the equipment to let you know it has been done.
- We have squares, micrometers and Vernier callipers. These are the measuring instruments, and they are calibrated once a year, at least. We send these out to a lab that specializes in calibrating and they come back with a certification with a date on it. There is a master file kept on all of the measuring instruments and a sticker placed right on the instrument itself.
- There is a lot of work to start out, but now that we are using them, staff all pay attention to the way instruments are handled and take care of them much better. They keep them in their cases and store them at the end of their shift.
- By measuring the product correctly, we can spot defects much sooner. The idea is to spot the defects while the product is in process, rather than wait until the final inspection.

### 12. INSPECTION AND TEST STATUS

Make sure you are able to tell if what you are working on has passed whatever inspection is called for up to that point.

Indicate clearly on the product who has the authority to sign off that the product meets standards. Throughout the process of development and approval, also indicate on the product the stage of the process the product is in and the results of reviews up to that point.

- We put out very detailed test reports. When we sell equipment we are legally liable for it. If a radio does not work we have to ensure we have tested it for FCP part 15 and submit a copy to the government. We have to be able to prove we tested it to requirements. ISO ensures we keep those reports in an orderly way. It ensures we keep standardized test procedures and that everything that comes through is tested the same way. It goes through a rigid set of steps and the way we do the testing and the way we do the reporting is standard. We check to make sure all equipment is calibrated. Now it is all in calibration, and now it is rotated on a regular basis.
- It gives you control you know what is going on. Now you know you are doing it right. Plus, you know it wasn't someone in head office writing procedures, it was us together who knew the job. You tell us what you need and we will tell you how to get it that way.
- We put a sticker tag on it and as we go along we mark the tag. We keep a log book of what is happening to it, and keep track of what tests have been done and where it is going next. Once the system is in place you have to make sure people use the system and be sure everybody is trained on it. It is easy if you use a log book and sticker system.
- We use stamps and tags to identify the stage that a product is in. The product gets a stamp to say it has been approved to go on to the next stage. A report is written after about 100 units are completed, and in it is indicated that, for example, six units were deficient. The ones that are bad get tagged with a non-conformance tag. They are tagged in a way that shows if they can be repaired or reworked. It is recorded on the document and it goes to the manager, who reviews each report. Every test we do is recorded.

Anyone in our plant can tag a non-conforming product. Nobody other than the inspection group is allowed to pull a tag. If you are not a qualified product inspector, you cannot change the designation of a product that has previously been rejected.

Requirements

ISO 9000: MAKING QUALITY HAPPEN.

## 13. CONTROL OF NON-CONFORMING PRODUCT

Put a procedure in place to handle products or services that do not meet the requirements laid out for them. This can involve either re-working or scrapping them. Once any corrections are made, the products should go through the same review stages as the originals would have.

- Non-conforming product is taken out of the stream and a decision is made as to whether it can be put back into spec by simple operations. If it is too far out of spec it is scrapped. Non-conforming product is identified by tags to keep it separate.
- This is something you just can't mess with. Everyone is schedule driven. People don't want to hear bad news so the only way to get it done is to do it formally. You have to make sure it is taken care of and you don't want any doubts. There is no way to do it informally you hold their feet to the fire.
  - We try to be both cordial and yet pretty business like. It helps if you are easy to deal with. It is a continuing relationship with these people and they understand you are doing your job; we are one team and that is a big thing.
- We say that 75% of the time we are under four hours to all service calls. If one district falls short and you are at 70%, they issue a Non-Conformance Report (NC) because they have not conformed. The NC is routed by the quality manager to whomever appropriate, first to the district service manager and then to the regional office. On a single page the NC shows the non-conformance, the corrective action (what to do to correct it), and the preventative action (what to do to stop it happening again). ISO says the NC must be answered and the quality manager sees that it is.
- The NC hits me within two or three days, and soon there will be a time limit set on responding. The person who sent in the NC gets word back as to what the corrective action is. It is a tightly controlled process and now everyone is on board. We do not use NCs as a performance appraisal. We are now changing them to reflect the degree how often, how badly. They catch the major problems. Most of what I feel is really important has gone in. The quality manager gets the data to be able to determine if there is a nation-wide problem.

In our operation we put on a tag that you can see from 50 feet away, so it can be identified from a front-end loader and so it cannot get mixed up with product that is good. Even if it gets through, the next guy can see it is a rejected piece of material. On the tag is written who rejected it and the reason. The loader picks it up and isolates it in a location in the yard for that type of material.

3-29 Requirements

### 14. CORRECTIVE ACTION

As soon as a problem has been found, begin action to correct it. Corrective action involves more than one-time firefighting. It also includes investigating why the problem happened in the first place, and what can be done to prevent its happening again. This is going to involve looking in depth at the whole picture: the way the work is done, including policies and procedures, and any reports on what has been done to date. It is a good idea at the same time to think about and try to eliminate anything that might cause a problem in the future.

The next step is prevention. Choose preventative actions with an eye to the significance of the risk they ward off; the benefits should be greater than the effort. Be sure to apply controls to see that the actions are in fact done, and that they are effective. Finally, implement the resultant changes into the standard operating procedures. This may involve additional training for staff.

### Comments

- back to the step where the problem first occurred and start over from there. You can't cut corners. You solve the problem and you also take note of what caused the problem and see that the cause is removed. It has to start from the worker bees and work its way up to managers and on up the hierarchy to what ever level is resposible.
- We have a good system in place for recording our findings from internal audits, and a well-defined process for resolving any non-compliances. This is a pretty sophisticated place that follows up on things, and that is so important to the success of the program.

If we find a non-compliance that occurs because the defined process does not meet the requirements of the standard, we assign the corrective action to the process owner. If we find a non-compliance that occurs because the defined process was not followed, then the manager responsible for the person who did not follow the process is assigned the responsibility.

The person responsible for resolving the non-compliance must identify the root cause of the problem, why it was possible for it to happen, and develop and implement a corrective action plan to prevent recurrence. The corrective-action plans have to be provided within a specific time, and there is a closed-loop system to ensure corrective actions are implemented.

In most cases the root cause turned out to be they didn't have training or the training was not sufficient. Then, the process owner is assigned to make sure the training is complete. In a minor number of cases, a modification is needed in the process, to adapt it to a specific area. Where a modification is needed, or the training as designed is not sufficient, the implementing manager works with the process owner to identify what changes need to be made. The process owner keeps control of designing the process, to make sure we are continually working toward best-in-class processes.

Regarding modifications to equipment, we now have a good process. Every reliability graph is going up, because we have a formalized corrective-action plan in place now. We had one before, but no one paid any attention to it. Guys do fill in the non-conformance reports and head office answers back and is right on top. I see it is working and I am happy.

# 15. HANDLING, STORAGE, PACKAGING AND DELIVERY

This category, when applied to manufacturing, refers to the care and procedures needed to ensure the finished product arrives in good condition at the customer after it is completed. It requires checking the condition of the stock at appropriate intervals and ensuring the stated quality is preserved.

When applied to services, it refers to the way the client receives the service. It involves three steps.

## Design the service to meet the requirements of the contract.

Describe each part of the service in written procedures that break down the tasks into understandable parts. Give staff the training they need to be able to perform these tasks and to understand their importance for meeting the organization's contractual obligations to the client. Managers make sure no one does the work who is not trained for it. Review training to see it covers everything, but does not take more time or resources than needed to get results.

Set up a way to deliver the service so that it meets the requirements of the design.

The Service Delivery Procedures are the step-by-step work breakdowns of the way the service is provided to the clients.

## Listen to clients and their opinions.

The clients' evaluations will tell the organization how well the clients think the organization met the service agreement written in the Service Brief.

# Questions

Do you ensure the planned activities of the staff will be consistent with the policy?

Are staff given the training they need?

Do you have a way of knowing whether staff implement and adhere to the policy?

Does your staff understand the significance of their tasks in relation to the result the client receives?

Does your staff have the freedom to adjust the service to accommodate exceptional cases that meet the spirit of the policy?

How do you know your picture is accurate and complete?

Are you alert to changes in what the client wants?

Are staff receptive to clients' suggestions for improving the service and do they actively seek out these suggestions?

Do you have a way of receiving and using suggestions and comments to improve what you do?

Are clients aware of how their comments could help improve the service? Are clients offered a summary of comments and suggestions?

Are clients told about changes made as a result of their suggestions?

### Comments

We used to buy from 40 vendors, and we bought in quantity. It sat in inventory for months. Then when we used it, it didn't work. We bought in bulk before to take care of problems, in case a line went down. Now we can get a supplier in within a day.

Inventory levels were a big problem. The cost of carrying it went to the bottom line. That is what we needed to reduce. We used JIT, a pull instead of a push. Before, we made 50 kits at one stage to be used in the next. Then that next stage started with those 50 and so on with each stage. We now have a 'kanban' stock. We may need six core systems on hand complete. When a customer gives us specs we pull a core system out and pull out the special parts to configure it for the customer. Pulling one core system triggers the manufacturing line to produce another one and that goes right back to the supplier. We give the supplier visibility as to what we want, when and how many, so their delivery is part of our overall measurement. The supplier can then himself determine the buffer stock he keeps on hand for us. Then he can reduce the inventory to meet our needs. Until we get product we don't have to pay for it. JIT is based on continuous removal of waste.

One of our suppliers has a six sigma program. We met them and they put a process in place in their warehouse to meet our requirements. They now use that for others. They tell us we helped them improve their quality. We learn from them as well.

We do tests on the packaging and on the equipment. We test it in a machine that simulates the back of a truck, testing for vibration effects, packaging and unpackaging and earthquake effects. We drop the product with and without packaging on all four corners from specified heights. It has to remain operational. It is all outlined in our procedures and in the regulations.

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Requirements

## 16. QUALITY RECORDS

Be able to demonstrate you met the level of quality you promised, and that the operation of the quality system was effective.

Keep track of what you do and ensure you are aware of the results of what you do. Gather hard data about the key factors that affect the client's perception of value. Staff should keep accurate records of activities, and use these records to ensure goals are met. Performance indicators should measure the results of interaction with the clients as well. Make sure your performance indicators give you the facts you need to help you meet the requirements of your contract with the client.

Make sure you can get at the records easily. Decide in advance how long you will keep the records, and indicate this retention time.

# Questions

Is there anything you measure that you do not need for the purpose of ensuring meeting the requirements of the contract?

Does your data collection give you everything you need to get the facts about your service on the table?

Does the benefit you gain from the data gathered justify the time, energy, resources and disruption to clients caused by the method you use to gather the data?

- In R&D our goal is time to market. Before, whatever our engineers could dream up, the marketing people could flog. We had the only thing on the market and the customer paid a premium. Today cost and time to market is vital. Our job is to get the product to them ahead of the competition, and ISO certainly helps us to achieve that. With new products that hit the floor we aren't finding the same kinds of design problems as years ago, and they are largely eliminated. We monitor the number of ECOs and that has gone down drastically.
- Quality falls in with reliability. It has to do with knowing how much to charge on service contracts. They go out every quarter and ask the customer to rate us one to ten on a number of features, such as reliability, servicing, response time, technical expertise and courtesy, and we ask them where we need to improve. They ask every one of our customers by region, by state and by company. They bring our customers in to talk to us. Everyone here comes in and listens as they tell us what they think of us and what our strengths and weaknesses are. The

information is published to everyone in the company, through one of our internal newsletters or magazines.

- We take customer complaints and log them by product. It is a big priority. We set up a big database system to store the information. It took a lot of work to set up but we make sure the clerk gets everything. The system continues to evolve as we work. Cross referencing is key, because something may be part of a different product or project, and it can be difficult to search for.
- We have records for every cost element. For physical inspection, for example, we know how many we looked at, how many defects, and so on.

The records are summarized on a monthly basis. We have all the information and a unit cost applied to that summary so we can apply monthly costs to monthly product.

We then assess them. If they are not on target we analyze why the numbers are off and how we can fix it. There are no surprises.

The individual records are kept on file for the life of the product. We store the information in environmentally sound conditions in a dry storage area. They are coded and dated.

We are looking forward to having inspectors use hand-held computers for notes, so they can just plug them in at the end of the day and dump the information straight into the central computer. Then we can have the input checked for mistakes on screen by the clerk, who will verify it and apply it to the inventory by just pushing a button. It should speed things up and make things easier.

## 17. INTERNAL QUALITY AUDIT

Internal quality audits verify the effectiveness of the quality system. Audit regularly according to an established schedule and follow standard procedures. Document the results and bring them to the attention of those responsible for the areas audited, who should then take timely corrective action.

Lars Ingram, in an article in the October 1991 issue of <u>Pulp and Paper</u> entitled "The Quality Audit," calls audits:

a process that helps uncover new opportunities and remove barriers that might impede the continuous improvement process. People must go into the audit with the objective that everyone is to benefit from the experience. Audits verify that all quality system elements - procedures, processes and people - are functioning effectively.

To complement the formal audit process, effective organizations have an internal process as well. They ensure that the comments of staff on the service, and on how clients react to the service, are sought out and used in the evaluation of the service. For this to work, staff need to feel responsible for identifying potential gaps in service. They should reflect on the service the organization offers clients, and on how to improve it. For this to happen, staff have to have a way of making known their evaluation of how well the program is working.

- We do audits on a process basis, for example, on the testing process, and also on a customer-feature basis, and follow the feature through all of the development processes for a particular customer feature and through all the processes in its development life cycle. After a year of internal auditing we are finding fewer non-compliances, and we see the internal-audit program as an integral part of continuous improvement.
- We found the audit process helped keep the manual realistic. People will overdo the requirements to look good and then get audited on them. The internal auditors have them take out any requirements they can't live up to. ISO talks about the minimum, not the ideal. We caution them that if it is not workable and you can't fulfil it you will get a non-conformance.
- We use five people to audit the 16 units in this plant, covering 300 people. The entire process takes about two months of the auditors' time, beginning with notifying the units until the sign off on corrective action. The finished audit

report is kept on file, and includes the original audit checklist, the status log of correction requests and the requests themselves.

We do one internal audit each year. Our audit cycle includes the following steps:

notify
check list
set times
meet supervisors
read books
do audit
do corrective action requests
review corrective action suggestions
see they are done
sign off.

- I am both an auditor and a service representative, so I know the procedures from experience. I do audits a few times a month, on a random basis. By now, I find people are coming to me to ask me to audit them, because they want to make sure they are doing everything the right way.
- When I am on an audit, I first ask questions about the procedures. If the person I am auditing doesn't know one of the answers, that's alright, as long as he knows how to find it out. For example, if a piece of equipment is damaged, he should know how to use the manual to find who to call and what to do. They don't have to know everything from memory, because it is all in the manual. I also spend a whole day with the individuals I select for the audit. I pay attention
  - I also spend a whole day with the individuals I select for the audit. I pay attention to how they act with customers, such as how they answer calls, and how they listen for their needs. Another thing I do is look to see if the parts inventory binder is in the car and up to date. We are supposed to keep a full stock of parts in the trunk and a list in the front of the car. The guys used to keep the list in their heads, but when someone else had to use the car, they had no idea if all the parts were in the trunk.
- ISO internal audit provides an excuse for the manager to get on to the shop floor. We have managers participate in the audits. That gives them an excuse to meet staff and see what they actually do. When the manager does the audit he walks away with a very good appreciation of staff, and they see he knows what their job is. It increases awareness and helps structure behaviour. It shows a commitment, and the shop floor knows the manager is serious about quality. It also gives an audit readiness signal and improves communication and understanding.

#### 18. TRAINING

Effective management of training demands that the organization identify the training that each position needs to be able to guarantee quality work. The training needs of a position do not need to be extensive or elaborate, but they do need to be clearly described if the organization is to be able to meet the needs. The training needs identified may cover areas not previously considered.

The next step is to provide the training. This means supplying enough resources in a timely manner. Then ensure every person performing a task has the training needed for that task.

Finally, be able to demonstrate evidence of training. This requires an inventory of training that has been completed and a database of the training and qualifications of each staff member. These records should be available by position as well as in the individual's personnel file.

On a regular basis, review that the training produces the results it is supposed to.

#### Comments

- Here, people get the training they need. People hate to do things they don't know how to do. Now management says okay, we will teach you how to do it.
- During our internal audits, we found that most non-compliances were from either a lack of training or a deficiency in the process. We simply didn't find that people are wilfully not doing the job. People want to do a good job, and if they are not following the process we find there is always a good reason for it.

Because a lack of training is such a common cause of non-compliance, we make the managers responsible for getting people the training that they need. That emphasizes to managers the importance of training, and staff are better trained as a result.

Sometimes a non-compliance results even though people have had the standard training, because the training didn't cover everything it should have. The responsibility for this does not fall on the manager, it falls on the process owner, whose job it is to design the training and make sure it works. The process owners are responsible not only for the definition of the process, but also for providing the training and for the plan-do-check-act process improvement.

In our economy today, training is a big thing. People interchange jobs all the time. Now we have a formal training manual, including how to train a new person. Working from your own notes in a book in your back pocket won't

- produce a quality product, it will just produce more fires to fight and more waste. Now we don't pass on bad habits to new people, and everyone uses the same procedures. It makes it a lot easier and helps people work.
- Before, work here was repetitive motion. Now we give staff flexibility and move them everywhere. The person you work with today may not be the one you work with tomorrow. Training was big. Our own people put it together themselves and put it out. Our people are smart people. All they need is a channel to let them let it out. We still keep training here even during downsizing. Our people do the training.

#### 19. SERVICING

Products are produced to meet a need, but needs and circumstances change. As a result, products and services need to be reviewed periodically to ensure that the purpose for which they are intended is met. Effective servicing begins with effective marketing. Done well, marketing is the formal process of getting to know the clients. Marketing involves capting to understand the clients' peads, and at the same time letting the

is the formal process of getting to know the clients. Marketing involves coming to understand the clients' needs, and at the same time letting the clients learn about the resources you have available to help them. The essential idea is to make sure you and your clients have a good understanding of each other. This research should result in the organization's having a clear statement of the needs of the clients.

The client needs to be aware of how to change the contract that results from marketing. The client should also know about any standards on performance that the organization has set up, how to comment on them, how to complain and how to make suggestions to change the service.

The next step is to listen to clients and their opinions. The organization needs to set up effective means to get a complete picture of how the client sees the service, and to find out about any changes in the needs or expectations of the clients as they develop.

There should be consultation with the clients on how well what the organization sets in place works to meet their needs.

It is also important to make sure the staff's comments on the service, and on how clients react to the service, are sought out and used in the evaluation of the service.

The organization then combines the evaluations of staff and clients with the results of other performance measures, to establish how well it is accomplishing what it set out to do, and how the needs or expectations of the clients have changed.

Delivering quality service involves regularly adapting the service: renegotiate with clients the need you agree to meet, the service you offer to fulfil the need, the terms of the agreement or the way in which you deliver the service.

The key is internal communication. Make data developed in performance evaluation available to staff, and refer the data to interested areas. Staff promote feedback when they understand the goals of the program, the role and activities of each part of the operation, the effect of the work they do on the level of service the client receives, and their personal responsibility

for helping to meet the goals. Staff should feel responsible for making suggestions, sharing information with managers, colleagues and other parts of the organization, in order to help the organization as a whole to improve its ability to serve the clients. Managers should be open to comments and seek them out.

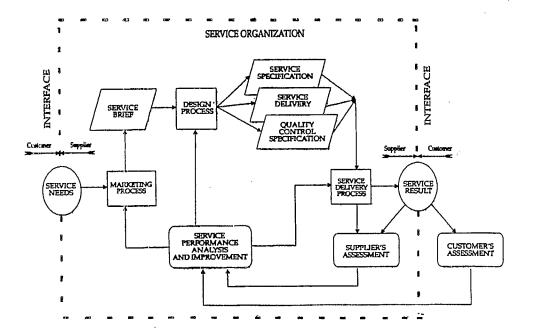
Each area of the organization assumes responsibility for seeking out and making use of suggestions from other areas. This feedback is promoted by a regular round of internal audits of procedures. Auditors verify that the area meets the standards it has set for itself in the activities that are essential to giving the clients the service they are counting on.

Make sure the clients are aware of how this flow of information takes place. In particular, the clients should be aware of how to renegotiate the Service Brief, and how their comments are used by the organization to improve service.

#### **Comments**

- Customer satisfaction is one of the most important things. There are a lot of good products out there, but the key is service, and 90% of service is how quickly you respond. You have to do what you say you are going to do. If the products break, get right there. The regulator allows us only six hours to fix any problems, and we have to meet that standard, day or night. We just have to get out there.
- Almost everything we make is designed with redundancies. If something goes down we have something else kick in, and that gives us the six hours to fix what went down. The key thing is to get out as soon as possible. We have people all over the world waiting for the phone to ring to get out there to act, and we have the networks set up so if our people don't know the answer they know how to find out fast.
- Customer problems come ahead of everything else. Managers tell us our customer is our priority. A customer could be inside or outside my customer could be another engineer in my group. We do what we say we do, and that includes getting the work done in a timely manner and doing the work as laid out in the specifications. We agree on what the regulations are and the customer requirements. If what we do doesn't meet them, we track it down, even if it turns out to be their problem or their equipment.

# Quality-service Feedback Loop (ISO 9004-2)



# **Steps to Service**

- 1. Understand the client's needs and the extent of the organization's resources.
- 2. Agree with the client on what can be done; be accountable for getting it done.
- 3a. Design the service to meet the accountability.
- 3b. Formulate the requirements for the service delivery.
- 3c. Design a way to ensure the service meets the accountability.
- 4. Set up a way to deliver the service so that it meets the requirements of the design.
- 5. Keep track of how well the sevice was delivered.
- 6. Listen to clients and their opinions.
- 7. Make sure staff's comments are sought out and heard.
- 8. Review regularly whether you accomplish what you set out to do.
- 9. Keep on adapting the service and focusing it on the client's needs.

#### 20. STATISTICAL TECHNIQUES

Measure the characteristics of any processes or designs that affect what clients say is the value in what they receive.

The techniques used must be standard and must be shown to be relevant and useful. Do not get bogged down in numbers if they do not help you improve. You should be able to show that your test is necessary and the results are accurate and are used.

There is no requirement in the ISO 9000 standards to use statistical methods, but where they are used there is a requirement to use them in accordance with accepted practice.

The simple fact that an aspect of the output of an organization is measured does not mean that the output is of good quality or that production of it is under control.

#### Comments

- It is key with any objective that it is measured. And people, given the objective, help to design the measurement. ISO provided the discipline do it right the first time, following procedure and we are still working on it. Supplier development was a big change. Four years ago purchasing was using PPV, looking to cut price, because price was the key variable. Now we look at Total Acquisition Cost instead. People have used measurement in the wrong way. Measurements have to be changed to keep up with what you are trying to do with your business.
- We keep statistics on failure rates. We try to pinpoint exactly how long the product will last. We measure according to industry standards of reliability, which lay out accepted procedures. Part of our quality policy is to do what we say we do, so we want to see if the product lasts as long as the warranty. We want to see if the product fails more that we thought. This helps us price our service contracts. If it fails less you can charge less. You don't want to overprice or underprice the contracts.
- For testing that incoming raw materials meet the purchase standard, we are going to use a statistical process by testing one in five lots, or some other percentage. If we find a problem we go back to testing every load until the product is up to standard.

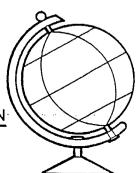
We know how many rejects we have at every part of the operation. That way we can know if there is a problem and investigate, even if we find there is a simple explanation.

We summarize and post the statistics. Our manufacturing team knows how many rejects we have at any stage of the operation, not just their own. We also post our financial statistics. Everyone knows how things are going. The guy on the shop floor knows what the management knows. It helps the team spirit, and they know we are not hiding things.

We are sending out a customer satisfaction questionnaire to get feedback on how they perceive us. Lots of times you are very surprised. We deliver 97.5% on time at the worst, we provide very high quality, and yet people may think we are a bunch of bums. If you don't find out what people think, if you don't get feedback, the day will come when you are out of business, and you won't know why. It is not the customer's responsibility to tell you. Often they won't. It is your responsibility to get it yourself.

# IMPLEMENT ISO 9000

ISO 9000: MAKING QUALITY HAPPEN



# **Implement ISO 9000**

# Six Steps to Certification

ISO certification takes place in six steps.

- 1. An application and a pre-assessment questionnaire are completed.
- 2. Employees carry out a pre-assessment audit, which can be conducted by a qualified third party as a 'rehearsal' for actual certification.
- 3. Pre-assessment activities identify any deficiencies in the existing quality system, which are then corrected to conform to ISO 9000 standards.
- 4. These preparations lead to an initial audit, carried out by an authorized ISO 9000 representative. The auditors may issue specific requests to change practices and processes that do not conform to ISO standards. These must be corrected within a set period of time.
- 5. Once deficiencies are acknowledged to be resolved, ISO certification is granted.
- To maintain ISO certification, the facility must have a bi-annual audit, which is done either by an ISO representative or an authorized organization. Every three years, the company's quality management system is re-assessed.

From Northern Telecom's Networking Special Report 1992.

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Implement

# What an Auditor Looks for in an Organization

Two lead auditors were asked where they would start in assessing a company that was seeking registration to the ISO 9001 standard.

- I would like to see the quality manual. If they don't have one, I would ask what type of written procedures do you have, where is it documented, how do people know what to do? I can't audit inside your head. It has to be written down, there's no two ways about it.
- I would want to see the management's commitment to quality and that they have a documented quality system, because if they do not have it documented it is not there. I would also check that the management has a quality and a process orientation, and a strong focus on continual process improvement. I would like to know who has responsibility, who has the authority not the details, but that it is there at the high level. That responsibility is the major thing.
- The first thing I would look for is this quality statement. Is a quality policy clearly visible and known to all employees? It should hit you like a Mack truck. It should be obvious. If I did not see it I would start asking people, and if they didn't know it I would stop the audit right there. Here all senior people have the quality policy in a frame in their office. It is in the main interaction areas where everyone can see it, especially the workers. It should be known by everybody in the organization.
- A key point is whether the people have the authority necessary to make the decisions to do their job, or are they always going to be second guessed. Are they forced to follow policy in their job and then the big guy comes in and circumvents the rules and looks like the good guy? Do you have the authority to do your job? It is no fun at all being given the assignment to do something but not having the authority to carry it out, with people coming from over your head and changing the decision you have worked on only to satisfy their whimsy.

#### **Case Studies on Implementation**

Every organization that implements ISO finds it leads to an ethical transformation on the part of its management. Some cannot adapt, and leave. Most find it leads to a personal evolution that brings them to new levels of passionate motivation and the opportunity for real leadership.

Three different people working in certified companies talk about how their companies undertook an ISO program. These are not company representatives and they are not conveying official company policy. They are talking about their experience as the program evolved. They give advice from their viewpoints on how to begin, what obstacles they found and what made it ultimately work. The companies range in size from large to small.

#### Case one

At this site, at first they thought it was just lip service. As they saw the upper managers getting more involved, they took it more seriously. It was mentioned at a general information meeting. The driving force has to be the CEO. There are few circumstances where it could work without his or her authority. Management responsibility is the first statement of requirements. They have to state their objectives and policies and commit themselves to them. They must make sure they are communicated effectively throughout the organization.

Follow-through is very important. Management has to do something to show them things will be different. An example might be weekly updates or ISO 9000 Employee of the Month. Keep it constantly on the minds and on the lips of everyone in the plant. We can't slow down. It is a whole lot easier to keep a rock in motion moving. An object in motion tends to stay in motion. Use luncheons and coffee mugs: make the people talk about it, make sure they know why they are there and why you are there.

Make the boss sell it to them. It should be clear: if we don't get this installed, heads will roll. If the boss makes directors accountable it will happen. You have to make managers get involved. Get them involved in the internal audits and aware of what is going on. Celebrate successes. If things go well, improve their performance reviews.

They sent me for a course, with people flown in from all over. They spared no expense, including full catered lunch and snacks. Spending money is one way to show they are willing to do something.

You have to start with management. It all starts from there. You have to get the commitment from them. You cannot fool the workers as to whether managers

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are serious. First get them to convince themselves that this is what they want to do. A half-way effort is not worth it. Don't interrupt it half way or it will annoy staff even more and make them realize the management commitment is not there.

Show them other large corporations are doing it, show them the logic of it: this is a structured way to manage people and things. It is going to make their job a lot easier. They are not going to have to be fighting fires all the time. A lot of people justify their jobs that way; a lot of those fires will be gone once you have a better structured way of doing things. You want an easier way of doing things.

#### Case two

We first had commitment from the highest level, saying we were going to get into compliance with ISO 9001 and get registered. The head of the business unit, the vice-president for the country, made the commitment.

Then we explained to staff why we were implementing ISO 9001, and we continue to have to do so. Here in this business unit, we already have a documented quality system in place, and although we have some gaps relative to ISO 9001, we are not starting from scratch. One thing we did have to do is to explain to the people in the organization why, with all that in place, we have taken on this commitment to achieve compliance to ISO 9000 and to get registered to it.

We had training for all managers on why we are implementing ISO 9001, and a half-day tutorial on the clauses of ISO, along with some interpretation and adaptation for our organization.

We did an analysis of our current quality-assurance system, and identified any gaps in compliance to the ISO 9000 standard.

ISO 9001 is strong on having quality records for everything and on where those records are stored. In our compliance analysis, we found that, although we did have quality records in place, we had to specify the retention times for the quality records and formalize that whole process more. Now we have set up the overall quality manual and put a process for quality records under that, and we have clearly defined retention times in place.

Although most of our processes are documented, we did find a few holes through our compliance analysis, and so now we are getting those processes documented in writing as well.

Another area we had to work with was to get a more formal process in place regarding our subcontractors. We do not necessarily require that all our sub-contractors be registered to ISO 9001, but we are reviewing their quality

manuals, and looking at the whole quality-management system of all our sub-contractors.

We also found some places in the quality manual where some of the responsibilities and authorities were not spelled out clearly, as required under the management responsibility section of the standard, and we needed to clarify those. We found that even where processes were already well documented, there were cases where the authorities were not clear.

We also did not have strong procedures for identifying what training different members of the organization needed and for making sure they got that training. We now have a process to identify training needs and a system for recording that they have had the training.

Now that ISO 9001 is implemented, we will audit all the processes ourselves all through the organization at least once a year.

#### Case three

In 1987 we had trouble with our customers because we couldn't consistently supply them with the material they wanted. It was a fix it or lose it situation.

I was given the job of writing the quality manual. You get this terrible feeling when you read the ISO specifications, because they don't provide you with the plain English requirements of what it is they want you to write and what it would mean to your company.

ISO is so barebones and generic. You need an individual who is capable of writing documents, you need the time commitment, or you need someone from outside to help. It takes a real concerted effort, not just by the person who is doing the writing, but also on the part of the operations people, because everything has to be reviewed.

Most companies do not have the documentation in place. You have to describe each action that occurs as the product moves from place to place. We had to get the operations guy to spend a lot of time with me.

You ask what you do next, what happens to it. He has to describe each process to you. You take notes. You then go back to your manual. You might see from the manual that you need to change the way they do it, for example, to become a controlled step. You have to tag the material to have proof.

You go back to your people and explain to them that this is how you have to do it now. They typically answer that they cannot, and they will have a list of reasons. So, you have to work with them to come up with something, but you don't want your quality system to impede your product.

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Implement

What I would do is cut to the bottom line and say let's talk about how we could do what you need to do and what I need to do. You come out with a way, and draft a procedures description, which is the heart and soul of the document.

Once the quality manual is prepared, the guy who is in the plant in operations knows exactly what he has in front of him and what he has to do. He knows what he needs, he knows exactly when to keep it back or change it, because he knows what will not work later in the operation. You do it right the first time and you will save money in your operation.

We used to have guys not knowing what the end requirements were. This cleans all that up, because everyone knows what everyone else has to do, what they need to have and what they should be doing. It saves everyone time and money. When people are well informed, everyone does a better job.

Once we finished doing the document and were implementing, we stamped it draft, because as we worked with the manual it became apparent some things did not work. Nevertheless, it gave us a start, and if we did not yet have what worked, we soon had a good idea what would. You have to almost re-write the thing. At that point you go for the registration.

The registration took place in 1989, but 1992 was the first year I felt the manual was really good. Getting the registration stamp is good, but if you have a good registration company, you are only going to get better. If they are diligent they will push and push. A good auditor will push you with good questions, and if you stumble, you have found an improvement. We have had three years of audits, and the manual just keeps getting better.

When we first put the system in, it was a hard sell to convince people that my time and overhead and auditing was anything but at cost. It takes a couple of years.

I got a shock when we took a survey and asked people what quality meant to them. Most people answered with my name. We realized we had a problem. Quality is not the person. The guy in that office is not responsible for quality, everybody is. Your heart and soul has to be part of what you do.

We had to work hard to convince the operations people how the quality guy fits in, and convince the people that quality is their responsibility. The quality guy just writes the procedures and so on. We told them the reason we make good products is not the quality guy. The ones who work with the product everyday are the ones who make it good.

I see why they get the perception that quality means the quality guy. The quality guy is always there when there is a problem, assessing it and changing the

procedures, and they saw me as taking the customer's side and not the company's side. Now they see I am in fact working for the company by saying not to ship a defective product.

ISO is only one element in our TQM process. The system gets you on rails. If you don't have it you don't even have your wheels on the rail. The tough part is to build a team, and this is harder because you are dealing with people's feelings. It involves training, communications in quality itself and time management. We have a bonus system, so that everyone is part of the profits. That is why everyone wants to know how we are doing.

Once the manual was written and interpreted, we looked for quick identifiable problems we could fix right away, and we started there, talking to the people and explaining about this topic. And now there is proof in the pudding for them, which is the profit sharing, the safety manual, sending people on courses, and demonstrating to them that we are concerned and want this to be a real team effort.

We threw a big party when we got the registration. We had the international president here, and it was in honour of the guys who worked in the plant, with no mention of the administrator in head office. It was to make them feel proud, with the board of directors and president here to recognize their efforts and say let's keep it going.

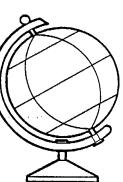
Whatever it is you do, if you look at it all at once it is complicated and confusing. Compartmentalize and do small sections one at a time. When you do finish one, take time out at each point and congratulate each other and pat each other on the back.

You have to watch that you don't end up just doing a lot of activities for the sake of activities. You might assume you are getting better from activities, but you have to be able to separate learning something from taking courses.

Be sure you are not going to get discouraged. Pick things that are achievable and measurable, where you can say you started it, you achieved it and you can see the results. Boom, there is one gold star to put on your page, and you can always show that you are going forward. When people can see they are making progress, they do not get discouraged and do not just go back to doing things the way they used to.

# 5 MAINTAIN CERTIFICATION: CONTINUOUS IMPROVEMENT

ISO 9000: MAKING QUALITY HAPPEN



# **Maintain Certification: Continuous Improvement**

# Sample Questions for Management Review

To maintain certification, the organization holds regular internal audits. Management reviews the audit results, promptly resolves non-conformances, and implements corrective action.

Below, are the kinds of questions that the organization asks itself to ensure that its continuous quality programs are on track.

Do we have a statement of commitment to quality by the senior managers?

Are all staff and clients aware of it?

Do we have a statement of the nature of the business, identifying the types of service and the clients?

Is it simple and explicit?

Do we have clear goals for our business?

Are our program goals comprehensive, in that they cover every part of our mission?

Can front-line staff recommend adjustments to the policy based on their experience?

Do we have an efficient way of using what the staff think of the program and their impression of the clients' satisfaction to improve what we offer and how we offer it?

Do staff feel responsible for making their comments and suggestions known to managers on improving the service?

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Maintain

Do they make known to managers what they need to provide quality service?

Are managers receptive to staff's suggestions for service improvement?

Do managers encourage innovation and continuous improvement?

Do managers feel responsible for soliciting comments and suggestions from staff, actively seeking them out and providing recognition, and considering them seriously?

Is our program review and evaluation process designed to ensure on-going improvement to the program's ability to reach its goals?

Do we seek out systemic errors?

Do we look for root causes of problems?

Do we make sure clients' and staff's assessments and suggestions are fully understood and used in the review process?

If a gap is found in service, do we root out the cause?

If we find a case of the policy not being implemented, do we have a way of making sure there is effective corrective action?

Is someone assigned specific responsibility for making sure corrective action is done in a timely manner?

Do we follow up to ensure the problem does not reoccur?

Do we feed staff's on-going experience back into the policy? Are the experiences of staff used to make adjustments to the policy?

Do we have a way of reviewing the assurance system to ensure it helps we meet the accountability and that the policy makes sense, given practical field experience?

Do we ensure any changes to the policy are understood and implemented in each area of responsibility?

Do we ensure all staff are aware of the goals of the program, the role and activities of each part of the operation, the effect of the work they do on the level of service the client receives, and their personal responsibility for helping to meet the goals?

Does everyone feel responsible for making suggestions, sharing information with managers, colleagues and other parts of the organization?

Does every part of the organization solicit suggestions from other parts of the organization they interact with, and act on them?

Do managers of each section feel responsible for working smoothly with every other section?

Do managers provide enough time and resources to staff to deliver good service, or else change the service?

# 6 APPENDIX

ISO 9000: MAKING QUALITY HAPPEN

# **Appendix**

#### Standards Council of Canada

A news release of February 2, 1993 announced that the first quality registration organizations were accredited. This is an excerpt from the news release:

The quality movement in Canada took an important step forward today with the accreditation of three quality registration organizations by the Standards Council of Canada.

The Canadian General Standards Board, in Ottawa, the Quality Management Institute, in Mississauga and Warnock Hersey Professional Services Ltd., in LaSalle, Quebec, became the first three bodies to demonstrate that they meet the requirements of the National Accreditation Program for Quality Registration Organizations.

Quality registration is quickly becoming an important component of trade. It is the means by which a supplier demonstrates to buyers and regulators that its in-house quality system meets the requirements of a quality management standard.

Increasingly, buyers around the world are demanding quality registration from suppliers. Most ask that suppliers be registered to one of the ISO 9000 series of quality management standards.

The Standard Council's accreditation program is aimed at enhancing the consistency and international acceptance of Canadian registration, thereby giving registered Canadian companies a stronger hand in markets where quality is a key concern.

The program will enable the Standards Council to negotiate mutual recognition agreements in the field of quality registration with other countries.

The National Accreditation Program for Quality Registration Organizations was first launched in December 1991 by the Standards Council of Canada, the Crown corporation whose mandate is to foster and promote voluntary standardization in Canada. The Standards Council manages the National Standards System and Canada's international standardization efforts.

Standards Council of Canada 1200-45 O'Connor Street Ottawa Ontario K1P 6N7

Tel.: (613) 238-3222 Fax: (613) 995-4564

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Appendix

# Bibliography

"Questions and Answers on Quality, the ISO 9000 Standard Series, Quality Systems Registration, and Related Issues"

#### Breitenberg, Maureen

U.S. DEPARTMENT OF COMMERCE REPORT NO. NISTIR Nov. 1991

Provides information on the development, content, and application of the ISO 9000 standards for readers unfamiliar with these standards. Provides sources of additional help. An authoritative, readable report on some complex issues.

#### "Behind the Façade of ISO 9000"

#### **Burrows**, Peter

ELECTRONIC BUSINESS Jan. 27, 1992

Discusses the pressures, particularly on electronics manufacturers, to comply with the standards. It also describes the confusion surrounding the standards. Contains a succinct presentation of the positions on both sides of the debate regarding the value of the standards for really improving an organization's quality. Also discussed are the "mind-numbing" aspects of choosing a registrar.

# "Exploring the World of ISO 9000"

# Byrnes, Daniel

QUALITY Oct. 1992

Reports on key issues related to quality management standards covered during Quality Expo TIME (Test Inspection Measurement Evaluation ) - International Conference in April '92 in Chicago. These issues included the basic functions and benefits of the standards, how ISO 9000 will work in Europe, registrar accreditation, ISO 9000 in the service industries, the registration process, the need for commitment by top management, and the role of a company's implementation team. These were among the issues addressed by a distinguished series of speakers.

#### "ICI Advanced Materials Implements ISO 9000 Program"

#### DeAngelis, Cynthia A.

QUALITY PROGRESS Nov. 1991

Describes the process the Thorndale Pa. plant was going through to achieve registration (expected by June '92) and how it related to the overall ICI program. Provides a list of Do's and Don'ts along with a number of benefits derived from the process.

#### "Planning a Successful ISO 9000 Assessment"

#### Dzus, George

**QUALITY PROGRESS Nov. 1991** 

Relates one Du Pont plant's experience with the registration process. Lists their 20 steps to registration, examples of discrepancies noted by the auditors, and the benefit they derived from the process; specifically, reduced process variation.

#### "ISO 9000 Standards - Aiming for Global Quality"

Ellasbek, Daniel E.

METALFORMING Mar. 1992

A primer written for the Precision Metalforming Association, covering the business reasons for and the value of complying with the standards. Outlines the process of becoming registered.

# "ISO 9000: the key to success in Europe"

#### Gosch, John

ELECTRONIC DESIGN Jan. 23, 1992

ISO 9000 is a set of quality system standards and guidelines designed to complement product or service requirements. It has widespread acceptance in Europe, and companies that intend to do business in the Single Market Europe after Jan. 1, 1993 should be familiar with it.

#### "ISO 9000: A Matter of Survival"

Hall, John, et al

INSTRUMENTATION AND CONTROL SYSTEMS Jun. 1992

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#### "Quality Assured: A Stamp for Survival"

#### Hendry, Ian

PULP & PAPER INTERNATIONAL Aug. 1991

While written for the pulp and paper industry, this article is useful for those in any industry. It gives particularly clear descriptions of the practical impacts a company that seeks certification can expect on their day-to-day operation. It also cites specific examples of the bottom line paybacks companies that adopted the disciplines obtained. The information accompanying the article shows the extent to which ISO 9000 has permeated this industry.

#### "ISO 9000: Choice or Necessity?"

#### Henke, Cliff

MEDICAL DEVICE & DIAGNOSTIC INDUSTRY Oct. 1992

Explains why, while technically voluntary, the ISO 9000 standards are tantamount to mandatory for the medical device industry in Europe. Describes the present situation between ISO 9001 and the FDA's GMP regulations. Also presents an overview of the ISO registration process, with some insights on selecting a registrar.

# "Facing the ISO 9000 Challenge"

#### Hutchens, Spencer Jr.

COMPLIANCE ENGINEERING Fall 1991

Provides background material on ISO, how the ISO 9000 standards evolved, the European Community, and the reasons for concern about ISO 9000. Contains an overview of the way the certification and registration process is controlled by the European Community and a description of the certification process from an individual company's perspective. The benefits of certification are outlined, along with an admonition to choose carefully. The explanation of the standards themselves is limited to a brief paraphrasing of the titles of the five standards.

"ISO 9002: The Exeter Story"

Inglesby, Tom

COMPLIANCE ENGINEERING Fall 1991

How one company succeeded in meeting this standard.

#### "The Total Quality System - Going Beyond ISO 9000"

Kalinsky, Ian S.

QUALITY PROGRESS Jun. 1990

Shows how the ISO 9000 standards can be used as the foundation to build a total quality system incorporates both competitive and industry / technology elements.

#### "An Insider's Guide to ISO 9000"

Kerr, John

ELECTRONICS PURCHASING Jan. 1992

#### "Achieving ISO 9000 Certification"

Kraus, Scott

PACKAGE PRINTING AND CONVERTING Dec. 1991

Cites the reasons people in the industry served by the magazine give for obtaining certification. Of special value are some "audit survival tips".

#### "Taking the Anxiety out of ISO 9000"

Kuhfeld, Ron

INSTRUMENTATION SYSTEMS Jun. 1992

# "ISO 9000 - Preparing for Registration"

Lamprecht, James L.

ASQC QUALITY PRESS AND MARCEL DEKKER, INC. 1992

This new book provides 'how-to' advice on, as its title says, preparing for registration. It also provides valuable information on other aspects of ISO 9000. It is a useful addition to the references of one responsible for managing an ISO implementation program. However, it should not be considered the definitive work on the topic. The user should be guided by, but not blindly follow his interpretations.

# "Quality Should Be Documented, Never Dictated"

#### Larson, Bruce

INTECH May 1992

Practical advice on ways to go about obtaining ISO certification, stressing the need to have involvement by those performing the work, in the creation and maintenance of the documents describing their work.

# "Quality System Registration"

### Lofgren, George Q.

**QUALITY PROGRESS May 1991** 

A look at the registration process by the president of the Registrar Accreditation Board (RAB).

#### "ISO 9000, A Universal Standard of Quality"

#### Marquardt, Donald W.

MANAGEMENT REVIEW Jan. 1992

Cites various reasons why within five years ISO 9000 registration will be necessary for businesses to stay competitive. Provides some useful pointers on how a company should approach the registration process. Lists a number of benefits DuPont facilities have reported as a result of ISO 9000 implementation efforts.

# "Vision 2000: The Strategy for the ISO 9000 Series: Standards in the 90's"

# Marquardt, Donald W. et al

QUALITY Aug. 1992

A long-range picture of international standards.

# "Selecting an ISO Registrar"

Savin, Stephen D.

QUALITY Aug. 1992

Contains an excellent chart showing relationships from a company through a registrar, to an accreditation body, as viewed by the European Community (and EFTA). Also gives a useful checklist to aid in the selection of a registrar.

#### "Selecting an ISO Registrar"

#### Savin, Stephen D.

QUALITY Aug. 1992

The article, covering registrars, deals with: Motivations for Certification, Conformity Assessment Systems, Infrastructure, Selection Process, and Benefits of Registration. The diagram of the International conformity assessment system is particularly useful, clarifying a number of confusing relationships.

#### "Insights into ISO 9000"

#### Sprow, Eugene

MANUFACTURING ENGINEERING Sept. 1992

In addition to providing basic information about the background to the standards, this article focuses on the benefits that can accrue to companies who implement them. Several examples are cited. The article also argues that while the standards do not specifically mention continuous improvement, the feedback process and the discipline ISO 9000 instills, form the basis for continuous improvement.

#### "What is the Registrar Accreditation Board?"

Stratton, John H.

QUALITY PROGRESS Jan. 1992

A description of the Registrar Accreditation Board (RAB); its formation, makeup, accreditation criteria, and accreditation process.

# "Quality is a Race Without End"

#### Veverka, Arthur

PULP & PAPER INTERNATIONAL Aug. 1991

A Europeans viewpoint on the difference in attitudes toward quality between North America and Europe.

# "Facing the ISO Challenge"

COMPLIANCE ENGINEERING 1992 Reference Guide.

Another good overview of ISO 9000 issues.

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# "Setting Up an Effective Calibration Program"

INSTRUMENTATION AND CONTROL SYSTEMS Jan. 1992 Special Issue QUALITY PROGRESS Jun. 1990 A series of articles on ISO 9000 issues.

# "How to Choose the Right ISO 9000 Registrar"

TOTAL QUALITY May 1992

Veterans of the registration process offer their advice for making what is not always a black-and-white decision.

QUEEN TS 156.6 .H8 1993 c.2 Hunter, Murray ISO 9000 : making quality ha

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