ISO 9000 Standard

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Introduction

ISO 9000 is a series of international quality standards based on British Standard BS5750. A plant can be registered to ISO 9001, 9002 or 9003.

To be registered to an ISO standard, a plant must successfully pass an audit from an auditing firm recognized by an accreditation body. Teepak has chosen Lloyds Register Quality Assurance (LRQA) which is recognized by the Registration Accreditation Board in the U.S.A.

The model in Figure 1 was developed by Ian Kalinosky and is described in an article "The Total Quality System - Going Beyond ISO 9000" from Quality Progress, June 1990. In essence, the top portion of the pyramid describes competitive elements such as quality/continuous improvement, customer service/satisfaction and control of costs. The industry and technology elements refer to safety/health, process control, automation and other research efforts. These items are absolutely necessary; however, without a solid foundation, they are not sustainable in the long run.

By using the ISO 9000 Quality Standard as a foundation for all initiatives and by enhancing and expanding our systems based on the Standard, we can achieve a total integration of the element on a planned and purposeful basis.

Once a plant has passed the audit, the plant must maintain the certification through, one-day, surveillance audits, twice yearly. After three years, the plant will be reassessed to the whole standard.

Overview of Standards and Elements

There are five documents which collectively comprise the ISO 9000 standard; 9000, 9001, 9002, 9003 and 9004. ISO 9000 is a reference document that clarifies the distinctions and interrelationships among the principal quality concepts and provides guidelines for the selection and use of the series of standards.

ISO 9004 is a reference document that describes the different elements of Quality Management.

ISO 9001, 9002, 9003 are the quality standards to which a plant can be registered.

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ISO 9001 covers the activities from design through production, installation and servicing.

ISO 9002 covers production and installation. Teepak has been registered to ISO 9002.

ISO 9003 covers only the activities limited to final inspection and testing.

Why should a plant be ISO-registered? Basically, there are three reasons to become registered. As a defensive measure, it may become a requirement of our customers. As an offensive measure, it may provide a competitive edge, particularly if we are first. But the most important reason should be that it makes sense to have a structured, documented approach to control in our systems.

ISO 9002 consists of 19 elements or requirements. The major focus is at four key areas:

1. Do you have a documented quality system?
2. Have you satisfied all the requirements of the standard?
3. Are you doing what your Standard Operating Procedures (SOPs) say you are doing? Is there documentation (records, data) to prove it?
4. Are you identifying and correcting problems? Are you continuously improving?

Management Responsibility. For these, the management's responsibilities include a Quality Policy signed by the plant's president or CEO; organization, responsibilities and authorities; quality verification (requirements, resources, and personnel); Management representation for ISO 9002; and management review of the quality system.

Quality System. Documented structure that insures that product conforms to specified requirements. Facility Quality Manual which outlines the polices and objectives, Departmental Quality Reference Manuals which describe the departments in more detail, SOPs which describe how work is to be performed and Quality Records which serve as ongoing evaluation tools, as well as objective evidence that the work was performed. For ISO expectation, a system is defined, functional and is in control.

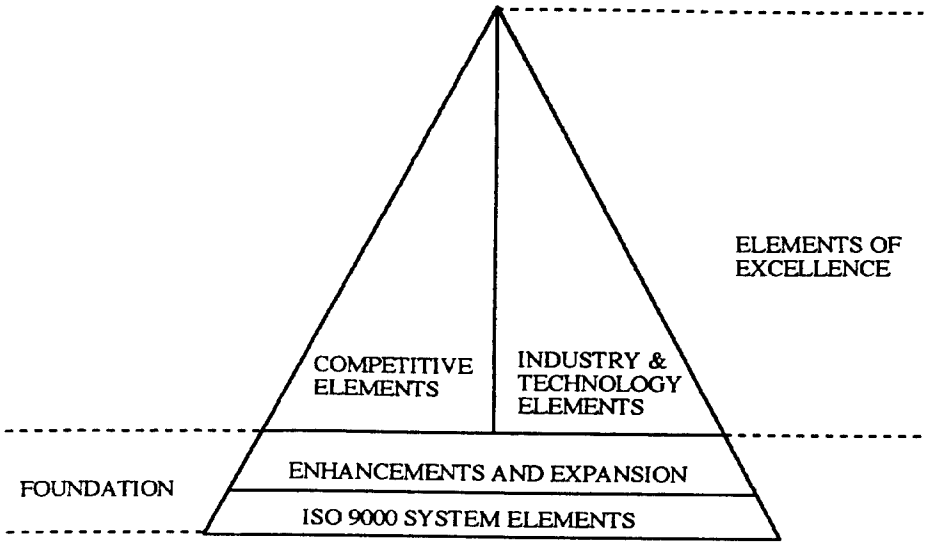
Contract Review. What systems are in place to insure that the plant has the capability to meet the requirements of the order or the contract?

Document Control. Are the documents and procedures in use controlled, correct and current? Are uncontrolled documents in use? Does the procedure reflect reality? Is the most current revision being used?

Purchasing. How does the plant make sure that materials purchased are confirmed to the requirements? Is the plant making vendor evaluations through performance measurements, visits and audits?

Product Identification and Traceability. How does the plant

Figure 1



Model for Excellence, from "The Total Quality System," by Ian S. Kalinosky, *Quality Progress*, June, 1990.

identify the product throughout the process? Is the plant able to trace back the product in case of a problem?

Process Control. How does the plant make sure the employees are performing to the documentation?

Inspection and Testing. Is the plant doing inspections and testing to document SOPs and specifications? ISO 9002 standard is making the following distinctions:

1. Receiving inspection and testing
2. In-process inspection and testing
3. Final inspection and testing
4. Inspection and testing records.

Inspection, Measurements and Testing Equipment. The plant shall control, calibrate and maintain inspection, measuring and testing equipment. The user of the testing equipment has to know that the testing equipment has been calibrated to do the testing. Calibration programs are critical for ISO plans.

Inspection and Test Status. Once the product has been tested, it must be determined if the product is acceptable for usage. The inspection and test status of the product shall be identified by using marking, tags, labels.

Control of Non-Conforming Product. If the product is out of specification, controls must be maintained to assure that the product is not to be used. Procedure to review the non-conforming products and disposition must be established.

Corrective Action. Procedures must be in place to review and assess actions to prevent recurrences of problems or products out of specification.

Handling, Storage, Packaging and Delivery. How does the plant control the warehouse, storage and shipping functions to insure no mistakes are made?

Quality Records. Quality records shall be maintained, identifiable to the product involved, and shall be stored to prevent damage and loss. Retention times shall be established.

Internal Quality Audits. These audits are reviews of the quality system, not the product. Audits will cover each of the elements on an annual basis. Audit teams members should be independent.

Training. The plant will need to identify who needs to be trained and in what; document that the people have been trained, and that they are qualified.

Statistical Techniques. Written procedures based on sound statistical principles and practices will be established.

Other Elements. Two more elements will be added to ISO programs. These are Purchaser Supplied Products and establishing and maintaining an effective Preventive Maintenance program.

ISO Registration Process

Document review is done prior to the registration audit. This is the review of the different Quality Manuals and the procedures. It takes one day by one person.

Registration audit is done within 90 days after the document review. It takes three days by two people. It can result in non-compliance notes. The reported non-compliances will need to be corrected by the their next visit. Too many non-compliances can result in a "hold point." Hold Points have to be addressed before the plant can be registered.

Assessments of hold points takes two days by one person. They have to be done within 90 days after the registration audit.

Surveillance audits are assessed on one day by one person, every six months. Results of the internal audit will always be reviewed. Specific elements of the quality system will be audited.

Every three years, the whole ISO program is reassessed.

Discussion

B. Savage: Are there any meat companies in the US that are ISO 9000-certified?

R. DeMoor: Not really. Several meat plants talked to us about starting an ISO program, but I don't think any are using it now.

G. Schmidt: Would it be fair to say that if a company has all their SOPs in place and uses them for training for every employee that's probably the foundation for ISO?

DeMoor: That's how you start. If you want to implement ISO, you make a chart of your product flow through your plant, look at all elements and raw materials coming in, what happens at each step? You then have specifications and SOPs, and you keep records.

Schmidt: So you start at the bottom of production?

DeMoor: At Teepak, we started with the cellulose and plastics manufacturing departments. Europe is ahead of us, so they had no need to improve their systems. They were interested in the economical value of ISO 9000 and included sales and marketing in the whole certification process.

W. Schwartz: You speak of many records and much documentation. Is that supplemented with your management information system and computerization, or is it all hard-copy paperwork?

DeMoor: What we did is centralize paperwork as much as possible in the computer system. But our operation's records are still kept manually. And though we have a computerized process system, half are manual.

J. Capra: How much does it cost to get certified? Does Lloyds pay for it?

DeMoor: It depends on the size of your company. For Teepak, I gave you an idea of the number of people we employ; the initial registration cost is $25,000 and the surveillance audit will cost $5,000.

Capra: And you have to do that every six months, right?

DeMoor: The $5,000 is done every six months. So the first year will cost you $30,000.

Capra: Whether Lloyds does it or another company does it, are they all recognized as being equal?

DeMoor: You have to be careful. You have to ask if they are covering ISO and ANSI. Some don't. I know if you go to Underwriters Labs or Lloyds and a few others, you shouldn't have a problem. There are, however, a few small ones operating that are shady.

R. Terrell: Yes, there are some charlatan-type operations. So I agree with Roger. You need to do some investigating.

Capra: This all sounds very similar to Total Quality Management plans except that it is overseen by an outside organization.

DeMoor: But it's different. I think you can take your program further than those 18 points. ISO is going to add a 19th point, which is preventative maintenance. You will have to demonstrate that you have a sound preventative maintenance program in place to guarantee the reliability of the equipment to supply the customer.

Capra: How much do you see this developing from your company? And how much developing in the US? Do you think it will become more popular?

DeMoor: It's becoming very popular.

Capra: Mostly due to the companies exporting to Europe now?

DeMoor: Well, yes and no. I know of several companies that only operate in the US. There is a company in the Danville area that manufactures cooling units and heat exchangers and has adopted ISO. Quaker Oats has too.

Terrell: The main philosophy of ISO is if you've been dealing internationally or plan to in the future. Most of the US companies who have dealt internationally are probably two-thirds of the way to ISO already because they've had many of these points in place. This just legitimizes their operation to the EC and other parts of the world. I'm not sure that it fits in the "mentality of the traditional meat processor."

DeMoor: When you make a final product that will be consumed by the guy in the street, he's not going to ask if you are ISO certified.

Capra: Do you have to be ISO-certified in order to do business in Europe?

DeMoor: No, there are some in Europe who are not certified.

Terrell: Your customer is going to tell you what you need to have.

DeMoor: My advice would be to use it in a framework of TQM. It is a very good check list and provides structure from all the different elements. Most of the time, TQM focuses on product quality.

Terrell: Roger, this is my personal fear of HACCP. We're going to oversell HACCP and the feasibility of ISO and we're still going to have a very narrow focus. So we're not going to fix the total business.

DeMoor: What does all this mean from an organizational effort? You're going to need a full-time, dedicated ISO coordinator. The first two years, this person will be dedicated to ISO for 100% of his time. Once everything is established, the attention won't be as intense. But this person will need to continue duties as an ISO coordinator. The organization itself will require quite some time from each department and group, like purchasing, processing, maintenance, etc. You have to form a project team which will review how well your SOPs are and in what shape your reports and paperwork are. You will be devoting at least eight hours a week per individual.

W. Means: Is there any investment of equipment?

DeMoor: Not as such, but you have to have good accurate means of calibration. You must have proper equipment to do an accurate job of calibrating your current equipment. In our case, that was probably a $15,000 investment.

Means: What do you expect for a pay-back due to your being ISO-certified?

DeMoor: It is tough to say. From a purely manufacturing perspective, it has reduced our number of man-hours and our number of defects. We have looked at it as part of our overall quality. A lot of pieces were already in place, but what we had to do was to put a structure in place. I think it's well worth the effort if you're after improvement of systems. But it depends on your customer. If they are final consumers, I believe that they are not going to ask if you're ISO-certified.