A study of the role and benefits of third party auditing in Quality Management Systems

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Industrial management and organisation

ABSTRACT

Purpose: Purpose of this paper is to study the role and benefits of third party auditing in ISO 9001:2008 Quality Management Systems which have been implemented. The review looks through the perspective of case studies from both manufacturing and service organizations. To enable the reader to understand the role of auditing the paper firstly explains the key principles relating to auditing quality management systems, the global trends relating to their implementation as well as third party auditing. Then the paper presents four short case studies relating to a hospital, ceramic tile manufacturer, a heat distribution organization and a gas equipment installation company – describing the benefits of third party auditing of their Quality Management Systems.

Design/methodology/approach: Used for the case study materials included the review of freely available case studies in the internet and through interviews of Senior Managers from the aforementioned Organisations.

Findings: Third party Quality Management Systems Auditing continue to be beneficial in a range of industry sectors and are still growing on a global basis.

Research limitations/implications: The study constitiutes a indication for other organizations to undertake introduction and certification of the management system based on ISO 9001.

Originality/value: The article presents representative values in third party audit processes, demonstrates results which may be used in the analysis of ISO 9001 implementation systems.

Keywords: Audit; Process; Quality Management Systems; ISO 9001

1. Introduction

The Quality Management System standard, ISO 9001 is perhaps the most popular product of the International Organization of Standardization (ISO). The debate about benefits of implementing ISO 9001 is never ending. Debates are opinions - so mine is as good as yours.

A Quality Management System is a framework based on a structured integration of best practice into operating systems

- frequently built around the cycle [1,6,9,13]:
- Plan - Has the manufacturer established the objectives and processes to enable the quality system to deliver the results in accordance with the regulatory requirements?,
- Do - Has the manufacturer implemented the quality management system and the processes?,
- Check - Has the manufacturer checked process monitoring and measurement results against the objectives and the regulatory requirements? Does the manufacturer evaluate the effectiveness of the quality system periodically through internal audits and management reviews?,
- Act - Has the manufacturer implemented effective corrective and preventive actions?.

The best businesses work as complete units with a shared vision. This may encompass information sharing, benchmarking, team working and working to the highest quality and environmental principles. A management system helps an organization to achieve these goals through such things as optimization of processes, management focus and discipline of management thinking.

ISO 9000 is a generic name given to a family of standards developed to provide a framework around which a quality management system can effectively be implemented.

The standard that will be most frequently cited in this paper is ISO 9001:2008 is the requirement standard, includes the following main sections [1]:
1. Quality Management System,
2. Management Responsibility,
3. Resource Management,
4. Product Realization,
5. Measurement Analysis and Improvement.

The implementation of an ISO 9001 compliant system must recognize that it is but a step in a long-term development of a continually improving QMS [13].

The benefits of implementing such a management standard and subsequent third party audits against it's requirements usually result as a direct consequence of the steps needed for it's implementation. Most frequently these include the following [9,13]:
1. Define why the organization is in business,
2. Determine the key processes that state 'what' the organization does,
3. Establish how these processes work within the organization's business,
4. Determine who owns these processes,
5. Agree these processes throughout the organization,
6. Define key performance indicators and establish objectives to monitor that the processes are delivering what is expected,
7. Verify the processes internally, and report to the processes owners as well as the Senior management to review improvement.

According to the requirements of ISO 9001, an organization must develop only six documented procedures: control of documents, control of quality records, **internal audits**, control of non-conformities, corrective action, and preventative action. A quality manual and records are also required. The development of other procedures, work instructions, and other documents is largely at the discretion of the organization. While auditing must therefore verify the existence of the necessary

documentation, it must also focus on the functionality of the Quality Management Systems [1].

Third party auditing of Quality Management Systems offers organizations help in achieving continuous performance improvement in the areas of business performance and risk management, by registering their management systems as meeting the requirements of a management system standards. The next section briefly summarises the key principles involved [11,12].

2. Auditing Quality Management Systems

The main principles relating to management systems auditing are defined by an International Standard, ISO 19011:2002 which provides "Guidelines on quality and environmental management systems auditing" for auditors and organizations needing to conduct internal and external quality or environmental management system audits, as well as on managing audit programmes [2]. This guidance document is also used by organizations involved in auditor certification and training, accreditation and standardization of management systems.
Definition of an audit according to ISO 19011: 2002 [2]:
"An audit is a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled".
Table 1 presents the key auditing principles.

Table 1.
Key Principles of auditing in the ISO 19011:2001 [2]

independence	the basis for the understanding and reliability of the audit conclusion
ethical conduct	the foundation of integrity and professional status
fair presentation	the foundation of integrity and professional status
evidence	the rational basis for reaching audit conclusions based on the application of defined criteria
due audit care	reasonable care in all matters and completeness in the presentation of the audit report

In order that these principles can be implemented in such a way that the organization derives most benefit, audits must be objective and produce information on which management can act to improve its operations. To achieve such a goal audits and audit programmes must be planned and managed, using defined methods and techniques. The intention is that audit evidence and conclusions will be relevant, reliable and sufficient. Obviously to achieve this the audit team members must be competent, free from bias and any conflict of interest. The relationship between the audit team audit's and client is one of confidentiality and discretion [11,12].

It should also be noted that the audit evidence relies on a sample of the information available, since an audit is conducted

during a finite period of time and it is therefore not possible to get access to and evaluate all of the available information and therefore identify all possible existing problems or nonconformities that may exist within the system. It is however, the aim to identify all trends that may be occurring within that management system under examination [10].

Although the principles of auditing are the same whatever the type and reason for it's execution may vary.

2.1. Types of audit

There are two basic types - external audits and internal audits. The Fig. 1 shows types of audit.
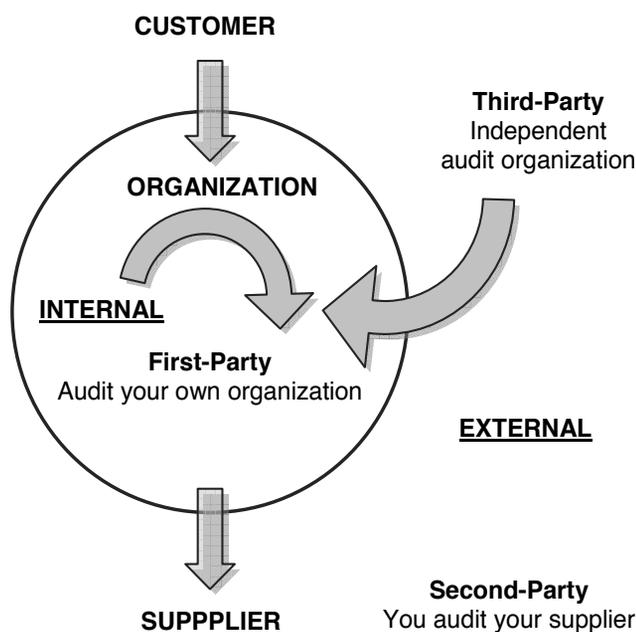
Fig. 1. Types of audits [7]

Characteristic of External Audits

These are audits carried out outside one's own organization and there are at least two distinct types of external audit – second and third party.

Second Party Audits

These audits, carried out by one company on another, originally came from the idea of a major supplier auditing its suppliers. There are a number of reasons why a company may wish to audit its suppliers. Reasons for second party audit include:
- that such an audit provides input to selecting, grading and approving the organizations own suppliers,
- that it provides a mechanism in the improvement of Quality Management Systems of suppliers,

- it increases mutual understanding of requirements,
- and in the case ISO 9001:2008 is a method of satisfying clause 7.4.1 of this standard.

Many major organizations carry out second party audits to advise user departments of areas of weakness in their suppliers so that appropriate contract and/or surveillance mechanisms can be instigated if the supplier is to be given work. It can also highlight any likely additional costs.

Third Party Audits (eg Certification Audits)

As a result of the huge growth in interest in Quality Assurance during the 1960s and 1970s, more and more second party audits were being carried out. Some companies in certain fields had to employ people whose sole task was to accompany visiting auditors around the company! Clearly this state of affairs was helping nobody, particularly the supplier. After considerable discussions at national levels, the BS 5750 scheme (now known as ISO 9001:2000) was introduced by the British Standards Institution (BSI) in the United Kingdom to rationalize all the assessment schemes as third party schemes operated by an independent body which would certificate companies as complying with the standard (or not as the case may be). Various bodies became certification bodies, and BSI Management Systems is a prominent example and became involved in carrying out independent or otherwise known as "Third party" audits [6,7,8].

First Party Audits / Internal Audits

First party audits are those which an organization carries out on itself to confirm to management that their documented management system is working effectively. Reasons for first party audits most frequently expressed include that they are
- a control mechanism utilized by management,
- used to correct nonconformities before third bodies find them,
- a tool to systematically improve the organization which is a requirement of many standards.

2.2. Role of Quality Management Systems Auditing

This issue has already been explored to some extent in the underlying reasons for the various types of audit. But these can really be summarized under one reason - SURVIVAL. In any competitive situation regardless if the organization is manufacturing or providing services, business will go to the more efficient provider. Auditing is a tool to inform an organization's management of the efficiency of it's processes – when carried out by Third parties it is not subjective and if a company is judged as meeting the requirements of a management system such as ISO 9001:2008 a certificate is issued which can them be used as a sign of acceptability to customers. It saves an organization from having to prove quality standards to discriminating customer and currently it is widely recognized worldwide so speaks an international language.

The popularity of ISO 9001 over recent years has increased significantly as discussed below.

Auditing is a tool of evaluation and improving of the management system. To the purposes of auditing belong:

- ascertaining consistency of the elements of the system with determined requirements,
- establishing efficiency of the introduced system to achieve particular purposes,
- enabling the registration of the management systems in the organization,
- evaluation of the fulfillment of requirements resulting from determined rules.

2.3. Global trends in Third Party Audits - Certification Audits

The Global trends for Certification (and therefore third party audits) have been monitored over a number of years by ISO - International Standards Organization which is the world's largest developer of voluntary standards. ISO does not perform certification to its standards but however does commission "The ISO survey" which is now in it's 18th cycle. ISO provides the results as a public information service on it's Web site www.iso.org [3,4,5]

ISO 9001 is by far the world's most established quality framework, currently being used by 1,064,000 organizations in 178 countries worldwide, and sets the standard not only for quality management systems, but management systems in general - data from 2010 [5].
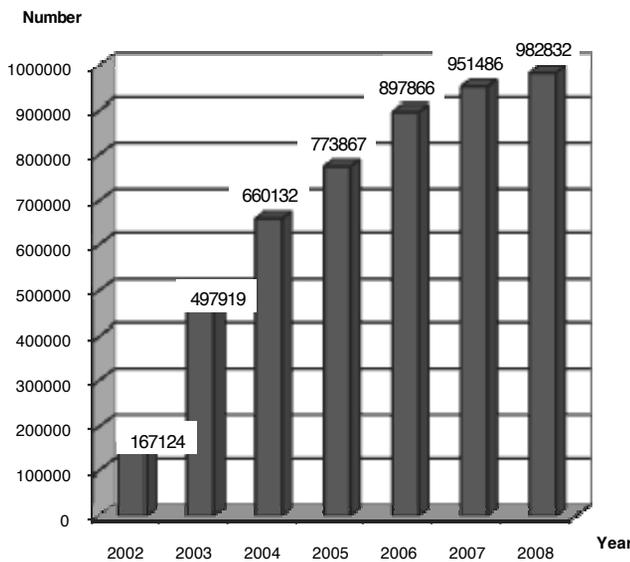

Fig. 2. Number of ISO 9001:2000/2008 certificates issued worldwide [3,4]

The Fig. 2 clearly shows the increase in number of certificates issues over the past five years and all indications are that this is continuing although the rate at which new companies are being

certified has slowed down to just over 120,000 companies worldwide in 2005. The Survey indicates that the Top ten countries for Quality Management Systems Certification against the requirements of ISO 9001:2000/2008 are presents in Table 2 [3,4].

Table 2.
Top ten countries for ISO 9001:2000/2008 certificates [3,4]

Country	No. of certificates	
	In year 2006	In year 2008
China	162799	224616
Italy	105799	118309
Japan	80518	62746
Spain	57552	68730
Germany	46458	48324
United Kingdom	40909	41150
USA	44883	32400
India	40967	37958
France	21349	23837
Netherlands	18922	-
Korea, Republic	-	23036

China and Italy recorded the highest annual growth of new certificates issued in Year 2006 and 2008 [3,4].

Looking at the results of this survey the trend appears to be continuation and growth of third party auditing and certification of Quality Management Systems with an extension into the number of countries in which companies/organizations are undergoing certification as below at the Table 3 [3,4].

The following Fig. 3 gives an idea of the number of certificates by top five industrial sectors [4].

Although this paper has focused it's content about Quality Management Systems there are others including:

- ISO 14001:2004 the Environmental Management Systems standard,
- OHSAS 18001 the Specification for Health and Safety Management Systems,
- ISO 27001 the Information Security Management Systems Standards,
- ISO 13485:2003 Medical devices - Quality Management Systems,
- ISO/TS 16949:2009 Quality Management Systems - Particular requirements for the Application of ISO 9001:2008 for automotive production and relevant service part organizations.

Table 3.
Number of countries for certification ISO 9001:2000/2008 [3,4]

Year	No. of Countries
2001	97
2002	133
2003	149
2004	154
2005	161
2006	170
2007	175
2008	176

Construction
76043

**Bask metal and
fabricated metal products**
64518

**Wholesale and retail trade; repairs
Of motor vehicles, motorcycles and
Personal and household goods**
46180

Electrical and optical equipment
42601

**Other services**
41404

25000   50000   75000   100000
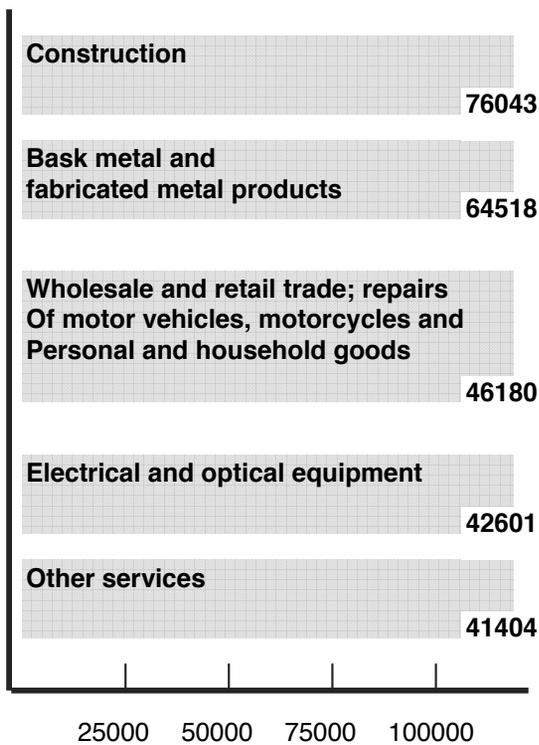
Fig. 3. Top five industrial sectors for ISO 9001:2000/2008 certificates [4]

The trend in all certification against the requirements of all the aforementioned standards is of growth and increased numbers of countries participating in the various schemes.

The 15th ISO survey shows that the next standard of interest relates to environmental issues with 54,593 companies being certified worldwide in 107 countries.

As certification requires third party auditing the global trend is that it is still seen as valuable tool.

The survey also shows that the type of organizations undergoing certification is extending so that it is not only the manufacturing companies but also service organizations increasing the growth.

3. Case studies

Presented below are the descriptions of a sample of organizations and the benefits they have gained from ISO 9001 implementation.

3.1. Microstructure

In this section there are four short case studies presented briefly describing the companies / organizations activities and the benefits that they have perceived from the Third Party audits (Certification audits) that they underwent.

3.2. Hospital, UK (Medical Imaging Department)

Background

The Medical Imaging Department of a UK Hospital offers a wide range of diagnostic facilities. It deals with around 90,000 patients each year and carries out around 120,000 examinations from chest X-rays and ultra sound scanning to MRI scans, CT scans and mammograms.

The hospital itself was built in 1983 and is a small district hospital in the United Kingdom. The hospital employs 1800 staff ranging from doctors to porters and serves a population of around 170,000. It is made up of a variety of different departments including it's own orthopedic department and specializes in day and short- stay surgery.

Customer needs

Two of the most important issues within the Medical Imaging Department are accuracy and safety. As the department's diagnostic services involve the use of radiation, failure to work to strict safety guidelines at all times could result in a danger to patients – for example through overdose(though such incidents are extremely rare). Strict guidelines are in force to ensure avoidance of error with regard to patient diagnosis. With these issues at stake, the departments' working practices are heavily regulated through by the government and any breach in regulations could result in the hospital being fined.

Benefits

The Medical Imaging Department's Quality Management Systems and it's third party auditing and certification have provided assurance that the department and it's staff are complying with the required guidelines. The Department's Medical Manager commented that "the ongoing assessments keep us on our toes. It is like a partnership. We benefit from out Certifying Organisation's observations but at the same time they often learn from our ways of doing things which can then be passed onto others".

Other benefits that were noted include:
1. Increased safety and welfare of patients,
2. Reduced insurance premiums,
3. Quality Management System is respected by other agencies dealt it.

3.3. Gas Heating company, UK

Background

This Gas heating company's is the largest domestic central heating and gas appliance installation company in the UK, providing customers with maintenance and breakdown cover. A growing part of the Group, includes a Gas company, supplying gas for residential purposes and an electricity supplier. The gas heating company provides care for its customers' central heating,

plumbing, drains, home electrics and kitchen appliances and installs domestic appliances and monitored home security systems. In 1999 it achieved ISO 9001 certification.

In addition, it has a achieved product certification for new central heating installations and in 2000 received a Queen's Enterprise award for the field system used their engineers. In addition to its contact centre staff, who also directly employ more than 8,000 engineers carried out servicing and breakdown services, looking after over 3.4 million customers.

Benefits

It was acknowledged by the Company that as a result of it's third party audit and subsequent certification both profit and customer satisfaction were improved in the company. Generally staff have been very positive about the disciplines that have been implemented, particularly where there have been improvements gained through operational effectiveness and focus. Additionally supplier relationships have become more focused and effective.

Savings that have been achieved through this process have included:

- Improved processing of service contracts 1,000,000 GBP,
- Reduction in unnecessary work 500,000 GBP,
- Reduction in duplicated visits 14,000,000 GBP.

In addition, it also underpinned the achievement of external recognition, including the Queens Award for Enterprise and Royal Warrant to the Royal Household.

Further developments

This company has gone on to develop an Environment management system as Energy Efficiency has proved to be an issue.

To ensure that the gas company manages it's impacts on the environment and identifies opportunities for improving it's performance, they are introducing environmental management systems (EMS) across all of our businesses.


Environmental Management System

Home servicing National parts centre Print centres Public sector division Sale and installation business
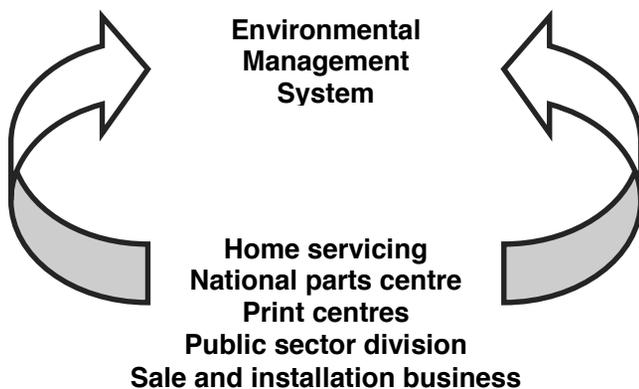
Fig. 4. Interrelationship between business units and the Environmental Management System

Management information

The Gas heating company has improved their fleet management information to capture better quality data on the fleet, focusing specifically on fuel used by each driver/vehicle. They benchmark performance data against other leading companies with similar vehicle fleets.

(They also identify high-risk drivers and provide training to help improve their driving style and reduce the potential risk of accidents). From 2004 the fleet specified operational vehicles with air-conditioning (A/C), a decision taken by the Head office to improve vehicle occupant comfort and safety.

To offset this increase in fuel usage, the fleet has equipped air conditioned vehicles with automatic switching, to prevent drivers from leaving the A/C permanently switched on. The fleet has specified vehicle top speed limiters. Both of these initiatives are aimed at reducing fuel consumption, and are ultimately aimed at recovering in full the increase in fuel consumption.

Waste and recycling

Businesses generate a wide variety of wastes. Office waste includes paper, cardboard and cans from their offices and call centres. Operational waste covers batteries, tyres, oil and used parts from the field engineers. Where such schemes exist, they try to recycle via local schemes that donate any profits to charity. The Head office's goal is to reduce waste sent to landfill sites by 15%, normalised against full-time employees. Fuel reduction.

All these areas are regularly audited to gain improved performance.

3.4. Ceramic tile manufacturer, Poland

Background

This Ceramic tile manufacturer is the oldest private manufacturer of ceramic tiles in Poland, which currently is one of the largest and most modern factories in the sector. The Ceramic tile manufacturer has a rich range of designs of assorted tiles for kitchens, bathrooms, floors ,decorative wall tiles and special tiles to order hand painted by artists.

The company built a custom purpose new fully automated manufacturing plant to enable it to meet it's customer needs as well as that of the local community in terms of the environment. Production lines have been installed in the production area which allow for single firing of tiles improving the productivity of the plant.

The ceramic tile manufacturer implemented a Quality Management System and underwent a Certification audit in November 2003 against the requirements of ISO 9001.

Benefits

During an interviewing with the Managing Director, there were many benefits from auditing the plant including:

- Encouraging employees to feel more involved through improved communication, whilst the continuing assessments carried out by BSI can highlight any skills shortages.

- Change of approach by the staff - a greater identification with the company.
- The assessment of the Quality Management System focused on the operating processes which helped to reduce waste and customer complaints.
- The implementation process ensured an improved the understanding of the processes in the Company and obliged the company to define the responsibilities and authorities of all staff, which were then confirmed by the third auditors. This gave the company a greater confidence that organization of the Management systems had been implemented in an effective manner.

Additionally, it also underpinned the achievement of the Award of the Construction Minister in Poznań 2007 for the best ceramic products and entry onto the Polish Stock Exchange.

Fig. 5. Award From the Minister for the Construction Industry - Poznań 2007

Further developments

The industry has implemented an Integrated Management System to include ISO 14001 and OHSAS 18001.

3.5. Heat supplying company, Poland

Background

This is a modern energy company specializing in the generation and distribution of heat for central heating applications and for heating of water for the two towns in Southern Poland.

The main activities carried out by the organization include the exploitation, conservation and maintenance of heating facilities, planning and executing new investments relating to heat generation and collaborating in the planning and coordination heat distribution activities. The organization implemented and underwent a third party (certification) audit according to the requirements of ISO 9000:2000 in 2005.

Benefits

During a meeting and discussion with the Vice President/ Technical Director, the benefits following the audit were discussed. These included:
- Ordering of documentation and records,
- Establishing and allocating appropriate resources for specific processes,
- Establishing process owners which has led to a greater care of them and their infrastructure,
- Systematic improvement in the cooperation between departments,
- Through quality management there is a noticeable increase in the flexibility and reaction time relating to client requirements.

4. Conclusions

In this paper four case studies were presented in diverse areas ranging from a Hospital, Ceramic Tile manufacture, Heat distribution and Installation of Gas equipment - companies which all have implemented Quality Management Systems and have had third party audits carried out. From the above and the numerous articles that were studied in the preparation of this paper (but are not described here) all had one element in common regardless of Industry, or country there were always significant benefits from implementing and auditing quality management systems (and now others too). The benefits that were cited most frequently were:
- Improvement of processes and procedures,
- Clearer definitions of responsibilities and authorities,
- Improvement in processes efficiencies depending on the type of organization eg/ reduction of waste, nonconforming products, service time etc,
- Improvement in customer satisfaction and reduction of customer complaints.

To conclude Third party Auditing of Quality Management Systems continues to be beneficial in a range of industry sectors and is still growing on a global basis.

An organization can implement the standards for their internal and external benefits without seeking certification. The decision whether or not to have a certified management system after an independent audit is one to be taken on business grounds – for example, if it is a customer requirement, or a regulatory requirement in the organization's area of activity.

Implementing ISO 9001 will offer challenges to all parties concerned - consultants, certifying bodies and organisations implementing the standard. If the requirements are implemented in letter and spirit, there is no doubt, organisations will stand to benefit and so will the customers and society at large. The demand for Quality Management Systems will only increase.

Acknowledgements

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