CERTIFICATION OF QUALITY SYSTEM

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ABSTRACT

This article deals with my own quality test practice I acquired when serving in a firm as a quality manager. I'm about to aim my attention to description of External audit procedures (so-called Audits made by Third Party – certification of the implemented quality system). Audits of quality relate to System, Process, Product and Personnel. They are significant when testing real situation, maintaining established Quality System and testing efficiency of Remedies.

1 INTRODUCTION

"An audit of quality is a systematic and independent Examination aiming to specify whether quality related operations and their results match to planned intentions and whether these intentions are realized efficiently and are appropriate for reaching the goals.
An audit of quality goes usually for Quality system or its components: it means Processes, Products or Services, but it doesn't specialize only to them. These kinds of audits are appositely referred to as "Quality system audits", "Process quality audits", "Product quality audits", "Service quality audits"**."** [ISO 9000-2]

An audit is a body of questions and answers (minutely tested theoretically and randomly tested in real operational environment). An auditor (questioner) mustn't ask just YES-NO-Questions, the responder must explain and substantiate the problem in detail.

2 TYPE OF QUALITY AUDITS

1. Internal (inter-company) quality audits:
   - so called Audits made by First Party – pursued by the tested object himself (organization, enterprise), who wishes to have its own quality system tested by a specific quality system standard;
2. External quality audits:
   - so called Audits made by Second Party – pursued by a Customer, who wishes to test his supplier's Internal Quality System, while realizing his own auditor's or independent

authority's potential.

- so called Audits made by Third Party – pursued by a relevant certification authority designated to perform tests aiming to certify and register Quality Systems of tested subjects; or pursued by an independent authority empowered to assign whether the tested subject's Quality System provides adequate product's quality operating management (for example Authorities active in Food Industry, Drug Industry, Nuclear Industry, etc.).

3 EXTERNAL QUALITY AUDITS MADE BY THIRD PARTY

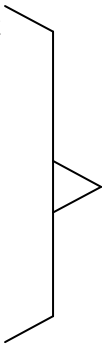
External quality audits made by third party (certification of quality system) are pursued only on contractual basis and they always have official nature.

We can distinguish between:

1. Pre-certification audit performed by an organization having the statute of accredited certification place. This kind of audit distinguishes between so-called "interim-visit", and "start evaluation" when both of them represent a kind of Consultancy. The certification authority's auditor assesses in short time the level of established quality system according to Standard ISO 9001. He aims his attention to just basic documentation. The outcome of auditor's work is not represented by Instructions how to eliminate traced Variances (just only if this is the customer's desire), he often just adduces examples of acceptable ways for their elimination. The auditor doesn't try to assess the efficiency of documentation; this is the topic for certification audit.
2. Certification audit goes after this Pre-certification evaluation of established quality management system.

3.1 CERTIFICATION OF QUALITY SYSTEM AND ISO 9001

1. Marketing and market research
2. **Design and development of a product**
3. **Supplying**
4. **Process Planning** (technology)
5. **Production**
6. **Inspection and testing**
7. **Packing and storing**
8. **Sale and Distribution**
9. **Starting up Operation**
10. **Service** (technical help)
11. After-use Liquidation



Scope of ISO 9001 Standard, in compliance with Certification of Quality System are performed

3.2 CERTIFICATION PROCESS OF QUALITY SYSTEM

The client's top management must clear the basic conception before start of this complex process (introducing and certification of client's quality management system). They have to specify in a clinical way the organization's organizational, technical and economic potential. This kind of rules will guarantee not only successful introducing of quality management system but also its process firmness. Also the client will be convinced of implementing his requirements.

The body of ISO 9000 Standards comprises basic requirements for a quality management system's introducing. But the way of this system's practical use has to be adapted for certain Product (activity, service).

The next step made by client's top management should be establishing partnership with a specialized consultant company. These experts realize informative ISO training course for members of top management as well as for wider group of technical and manual workers. A group of certified internal auditors are trained this way. These internal experts constitute then the core group of employees to implement the consultant company's instructions. They also behave as deputies when the consultant company is not present in place. They are responsible for those ISO problems besides their standard job. They are supposed to perform audits in internal workplaces above all when the aim is to assess the unity of working methods, system standard's requirements and internal instructions.

Implementation of ISO Standard's requirements to operational conditions then follows (changes and additions to ISO Standard's requirements are still possible). The phase of certification audits comes after which represents in fact an inspection of implemented system.

The first internal audit performed while cooperating both Consultant Company and internal auditors is to note facts (check of implementation) and to eliminate traced variances. The official external audit made by independent external authority (usually the same consultant company cooperating on implementation of the quality management system) comes next in short time (approximately in 3 – 4 weeks). If system errors are not traced the consultant company's activity in client plant ends.

The outcome of this external audit officially presented and consulted with client's top management represents significant information for certification authority whose activity will start in 3-4 months period (this period is necessary for the certification authority to be satisfied that the implemented quality management system comply with ISO Standards' requirements and mainly it is stable and viable).

Then the organization's top management selects a certification authority accredited for their country and registered with EOTC in Brussels (this authority helps to coordinate the whole Europe system of accreditation). After the process of auditor selection is finished and the contract is signed (it is common to send the application for audit performance in advance of 2-3 month period) the auditors realize first so-called Pre-certification audit aimed usually to the ISO documentation while they usually don't visit the plant (the client completes a basic questionnaire before for auditors).

Usually 2 auditors start the process of Pre-certification audit on the base of documentation obtained in about 1 month period. This phase of audit usually lasts not longer then 1 week (depends on the size of organization being audited) and it aims its attention to details in place also. The auditors test apart from actual findings also the former agenda, process and results of internal audits, summary of variances and customers' complaints.

The auditors present their results to client's top management immediately and then they write an auditor's report. The headquarters of the certification authority verifies this report before its sending to the customer. The report contains both real traced variances and traced suspicion of variances. The result is only warning of traced variances, not remedy suggestions also.

This certification audit's outcome represents final evaluation. It will be decided whether the client's application to get quality certification is going to be satisfy on its basis.

The members of an audit team should be the Chief auditor and one or more auditors who have to be internationally certified. An expert for the specific industry should be present too.

The auditors start their work by asking the client's employees (real situation survey) and testing operations on place, they analyze their findings then. They present their partial daily results every morning to client's management while workers responsible for those production or non-production problems are present also.

It's common to start the certification audit with marketing area, transaction from the system standard's list are tested. If a main Variance (system error) is traced it is not possible to recommend the Quality management system Certificate being made out. If no system error is traced, but only reparable imperfections are traced it is possible to recommend the Quality management system Certificate being made out with a note that remedies must be accepted and thus traced imperfections will be eliminated in short time period.

If one or more system errors are traced, this alternative treatment is possible (depends on the number of system errors and on complex condition of quality management system):

- next auditors' visit in place (usually in 3 month period), the auditors aim their attention only to those areas with traced system errors
- retake of whole quality management system audit

According to developed countries' statistics, where ISO Standards implementation is quite common, only about 25 % of plants are successful in first certification audit.

After satisfying all ISO Standards' quality system requirements the certification authority certifies this fact by making out the Quality management system Certificate. The Producer is besides the others allowed using Logo (the symbol of certification authority) in his correspondence, invoices, etc. from now on. The certification authority keeps on quality system supervision after making the Certificate out (usually 2x a year).

The Certificate is usually valid for 3 years period - on condition that short supervision visits performed 2x a year are successful. If a Variance is traced while supervising (but it can't be a system error – not acceptable variance) a special visit realized not later then in 3 months period must be planned. If this special supervision visit finds out that no remedies have been accepted the validity of Certificate will be called off then.

4 CONCLUSION

I think that in this area are more many deficiencies, which they can improve on. I am sure that it is better to do certification of quality system with using information technologies for clear and stereotypical activities by other orders of certification. At the present time I deal with improving on process of certification.

A great number of organizations go through the transformation process in our country. They wish to reach their targets – to become modern, flourishing, market-oriented companies which are able to quickly react to changes in customers' demand, to launch into market new products satisfying permanently growing customers' requirements. Nowadays those quality requirements are escalating it is necessary to implement and certified a functional quality management system in a plant to meet these targets. The Certificate of Quality attests the

quality of implemented quality management system and contributes this way to win customers' reliance in the organization's ability to deliver quality products.

REFERENCES

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