Project MOLE: continuing assessment to ISO 9000

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ABSTRACT

Many software companies with ISO 9000 registration are looking for ways for the registration to add value to their business. Consequently there is a demand for an IT-based system that will increase the benefits of continuing assessment. For the certification bodies, with clients demanding these new and better services, they need to offer improved approaches to assessment. BSI QA, Cranfield University and ICL Computers Ltd have developed an IT-based continuing assessment system, incorporating metrics to measure the "state of health" of the company's quality system.

INTRODUCTION

The "quality revolution" of the last decade was based on several factors. The perception that the Japanese success in penetrating European and US markets was based upon higher quality. The growing affluence of western consumers who started demanding greater product quality and choice, plus the realisation that the cheapest product to own is often the highest quality product, irrespective of sale price, were all important elements.

The software industry has had to participate in this revolution. Concern over software product quality has grown among consumers as it has become indispensable to their operations. IT
developers and suppliers are worried about software process quality as development costs and project leadtimes have become major issues for management attention. One response among software developers to these issues has been to adopt successful practices from other industries and adapt them to their needs.

A particular (and typically British?) strand in this adoption process has been quality system auditing and certification to ISO 9001/BS 5750 Part 1 (ISO 9002 and ISO 9003 are usually not applicable to software companies). Quality system audits began when military organisations in the 1940s and 1950s sent trained representatives to judge the technical and managerial capabilities of their suppliers. In the 1970s, the British Standards Institution (BSI) was informed by industry that a guide to auditing suppliers in the commercial sector would be useful. The BSI responded by issuing BS 5179 in 1974, and BS 5750 in 1979 (Khan et al [1]).

Suppliers can have many customers, and if each wants to audit, the burden on the supplier can be considerable. Suppliers began calling the BSI and complaining about the number of audits they were having to endure. In considering these complaints, BSI QA realised that just as independent financial auditors can audit financial accounts, so independent quality auditors could do the same for quality audits (Eicher [2]).

Independent, third party quality system auditing has grown and changed since these beginnings. There are over 20,000 companies registered and the number is still growing (especially in the IT sector) (HMSO [3]). Further, its success is beginning to lead to problems such as the growing (and possibly substantial) need for trained auditors (Vella et al [4]). However, one solution may be to connect the supplier and the certification body using an electronic link. This link can access the relevant data held on electronic media in the supplier's quality system and transmit it to the certification body.

Having access to the supplier's data could solve some problems, such as assisting the certification body in continuously monitoring the supplier's activities. But the full benefit would be realised if the system could measure, and report on the most
important measures of quality: those that give the most confidence that the supplier has an effective quality system. These measures or metrics will give the certification body an overview of the supplier's current quality performance. The certification body could identify those companies with stable and successful quality systems who may need fewer assessment visits than those with problems. The auditors would be better informed about the companies they are visiting, allowing them to direct their attention on the company's quality problems. Finally, it could provide a tool to improve the value of the audit to the supplier and the purchaser.

BSI QA, Cranfield University and ICL Computers Ltd are developing an IT-based continuing assessment system, to help measure the state of health of a supplier's quality system once they have achieved registration. A prototype system, MOLE (Management/Organisation Liaison Environment) currently connects BSI QA with a database containing quality information at ICL Computers.

AUDITING IN ITS BUSINESS ENVIRONMENT

Since third party audits began in the early 1980s, the relationship between certification bodies and suppliers (especially in the IT industry) has been changing. Historically, supplier audits were a means for a major purchaser to assure themselves that their suppliers could and were fulfilling the terms of the contract between them. Audits were arranged and conducted to satisfy the purchaser's needs. Sometimes suppliers were obliged to use procedures that fulfilled the purchaser's requirements, irrespective of whether they were beneficial to the supplier. When there were doubts or disagreements, the purchaser usually won.

These expectations and attitudes were influential when third party auditing began. But there are major differences between the two, and the consequences of this are still being understood. Possibly the most important difference is that the certification bodies are not major purchasers. The threat of withdrawal of registration may not threaten the supplier's business as much as the loss of a major contract. This is particularly so as certification bodies are reluctant to withdraw registration unless the supplier
fails consistently to meet its obligations. Purchasers do not have this concern.

There are many certification bodies offering registration. Suppliers are becoming aware of this choice and are demanding some value from the registration process, beyond reducing the number of audits that are necessary. In particular, suppliers expect the registration process, including the continuing assessment visits, to contribute to their quality system.

It is not yet clear what these contributions will be, however. One constraint is the accreditation process, managed by the National Accreditation Council for Certification Bodies (NACCB), for the Secretary of State for Trade and Industry. Accreditation demonstrates to purchasers and suppliers that the certification body "possesses the necessary competence and reliability to operate a certification system" (NACCB [5]). Maintaining accredited status is very important to a certification body, and these regulations influence the activities and services a certification body can offer.

It is in this changing business environment that MOLE will operate. Rather then being a 'more effective spy', it will provide accurate knowledge of the supplier's quality system. The certification bodies can use this knowledge in offering any new services, satisfying both the traditional clients who want to be assured that their suppliers possess a healthy quality system and their new clients, who want some help with their quality management activities.

BUSINESS REQUIREMENTS OF MOLE

One purpose of this project was to investigate the feasibility of developing a product based upon MOLE. Thus, some time was spent by ICL Computers Ltd in understanding what would be required to market the idea. They found the first requirement was the product would need to be cheap to own, both the software and the hardware to operate it. Although registration and continuing assessment represent a cost to the supplier, it is not major and could not justify a significant investment. The investment for the supplier can be minimised by using a standard hardware and
software environment, which the supplier is likely to possess. P.C.'s using Microsoft Windows® are common in many factories and offices, and their ubiquity makes them the choice for the platform.

MOLE needs to access enough information to make a significant contribution to the audit process; the more information it can obtain from various environments, the greater the contribution. Two things are needed: a significant fraction of the quality information must be held on electronic media and MOLE must be able to access it. Fortunately, IT-based systems to assist the management of the quality system have appeared, either commercial systems or systems developed by IT companies for their own use. If these systems become widely used, then much of the necessary information will be available. In addition, MOLE would only need to interface with one system, making the information transfer a straightforward process. Indeed, it would be possible to integrate MOLE with a quality system and sell them together. But now, much of the useful information is on paper, so MOLE will be useful primarily to a small (but growing) number of companies. Many of these companies will be in the IT sector, as they are taking the lead in adopting IT based quality management systems.

At present, suppliers use a variety of IT systems to support their quality systems. Management review meeting minutes may be held on an e-mail system and test and configuration management data on a stand-alone mainframe. Until IT-based quality management systems become commonplace or data interchange standards are adopted, MOLE may need to interface with several computer environments, even within the same company. To control development effort and costs, the customisation required for each application must be minimised. So it is probable that MOLE would consist of standard and tailored modules. In particular, the interface with the client's quality system and the auditor interface may differ for each application.

Discussions with potential users of MOLE showed that they expected MOLE to make a contribution to their company. It could, for instance, assist them in auditing and managing their own
processes. To reflect the needs of the internal and external users of MOLE, the prototype uses a hierarchy of functionality and data. The first level is aimed at the auditor, and provides them with summary information. This level would hold company details and the most important summary metrics describing the state of health of the company's quality management system, including historical data for trend analysis.

The second level will be able to prepare a detailed picture of the quality system. It would contain the information necessary to calculate the summary metrics, plus other useful metrics. It would contain more specific departmental information such as the departmental structure, document review records, quality review meeting minutes and the like. It would enable both an auditor and a quality representative in the supplier to monitor the quality system.

The third level contains the detail of the quality system itself. It may contain the project procedures, design and test records and other data that the company uses. Also it will provide the second level with the data it needs. The advantage of this structure is that it can reflect the way an auditor works. The auditor can scan level one and get an impression of the supplier. If they need more information they can access the second level and investigate the particular areas of interest. They may then be able to access the third level for specific enquiries.

MEASURING A SUPPLIER'S QUALITY SYSTEM

To produce an accurate and complete description of a supplier's quality system would mean analysing a great deal of data. Unless this data can be significantly reduced, so that a few key pieces summarise this description, the burden upon the auditor would not be lessened. One means of summarising the information is by preparing several key metrics. Using metrics should have several benefits. They can condense much information: for instance, the results from several audits or the trend in customer complaints can be displayed on one screen. The metrics can be displayed graphically, and the layout can be designed so that significant areas of performance can be highlighted and brought to
the auditor's attention. Metrics can be compared between different suppliers, and between different times to see if a supplier is improving. Finally, the metrics can be compared to predetermined values, to see whether the supplier has achieved a level of performance. Deviations from that performance can be monitored and flagged automatically. While developing the MOLE prototype, we wished to demonstrate the technology of data capture and analysis, and begin to use the system with BSI QA auditors. Consequently, we wanted to define three or four key metrics early in the programme, and add others as the prototype was developed.

It is the responsibility of the supplier to manage their quality system. The certification body uses audits to check that the suppliers are capable of this, that they have worthwhile procedures and skills in place. ISO 9001 requires certain procedures in an effective quality management system, both to ensure the system works properly and that the supplier can prove it (to itself and to others). Several metrics defined are concerned with ensuring that the supplier monitors its own performance. In particular, one of the most powerful of these monitoring techniques is believed to be the internal audit process.

Internal audits are very similar to third party audits. A skilled employee, independent of the department being audited, checks to see that a comprehensive, documented and understood quality system is being used and achieving positive results (Sayle [6]) (Hill [7]). Any areas of weakness should be highlighted by the auditor. These should be reviewed by management, so that they know the state of the system and can improve it by corrective actions. These corrective actions should not only rectify any weaknesses found by the audits, but proactively drive improvements in the quality system. As the certification bodies believe that an effective internal audit programme is necessary for managing an effective quality system, it is one key area of concern.

Specifically, audit programmes should cover all the supplier's activities regularly, thus they need to be planned. If these audits take place as planned, it is likely (though not a guarantee!) that management is aware of the performance of their quality system.
and that they are committed to the system. If the audit programme lapses, it is probable that the commitment to operate an effective quality system is lacking. So the percentage of the audits completed to schedule should be one reliable indicator of the state of the supplier's quality system.

Knowing you have problems is of no benefit unless you are prepared to tackle them. Nonconformances found by the audit are usually cleared by corrective actions. All certification bodies require that the supplier is "applying controls to ensure that corrective actions are taken and are effective." (BSI Standards [8]) If these actions have been taken, then it is probable that the quality system is improving, and completing the actions on time suggest a committed company. So the percentage of nonconformances cleared on time is another key metric.

One important category of nonconformance are those raised by customer complaints. Customer complaints are a vital source of feedback about quality system performance, as the primary goal of a quality system is to ensure customer satisfaction. Numerous serious complaints about the product or process reflect customer dissatisfaction. So for a company with a continually improving quality system, the number of serious complaints should decline. The trend in customer complaints is also a key metric. It is important to recognise here that, like all these metrics, several other factors affect the value of the metric. In particular, a company that encourages customer feedback is likely to receive more complaints than one which does not. Judgement must be used in deciding what the result of these metrics mean.

Although the internal audit process is an important means for management to measure the effectiveness of their quality system, it is not the only one. It is also necessary to review periodically all the documented work procedures to ensure that they are still relevant. Again, this review must be a planned activity with target dates set for the review. As with internal audits and corrective actions, commitment to the review should signify an effective quality system. So the percentage of documented work procedures reviewed to plan was the final key metric. Such a list cannot be complete, and many important activities justify the status of being
a key measure. However, certification bodies are concerned that suppliers are monitoring their quality system, and if that is happening it is likely that many other key activities are being properly managed. That was one reason these measures were chosen.

There were other reasons as well. One constraint is that the metrics should be easily measurable and expressed numerically (Watts [9]). So the metrics used to show the state of the process must be those that are relevant and are easily measurable. Consequently, aspects of the process that are easily measurable were chosen, as opposed to other, perhaps more valid measures that are difficult to express numerically. It is easy to find how many nonconformances were cleared as planned, how many resolved the problem is far more difficult to calculate.

With all measurement of individual, department and company performance, there is the danger that the concern will be to improve the metric, rather than improving the overall performance. For example, a supplier may rate corrective actions by the closeness to their due date rather than by the importance to the company, the results of the metrics would be improved but the company would not benefit. It is possible that less quality conscious companies could either "massage" their measurement process to achieve the results they desire or even cheat. For example, a company could decide not to report some customer complaints until a new accounting period had started or group together separate complaints from the same customer.

This is one reason audit visits will still be necessary, so that the auditor can judge the processes that the metrics describe, to understand the true performance. The auditor also would be needed to assess processes that are not summarised by the metrics and to maintain personal contact with the company. As the metrics cannot give a complete understanding, an audit visit would be necessary to establish the reasons for the poor performance and whether this was due to failures in the quality system or another cause. MOLE can highlight a problem, it is auditor judgement whether the quality system is at fault.
TECHNICAL ISSUES IN MOLE

The project partners have developed a prototype system to explore and support these ideas. The design (as of November 1993) has three main modules. The first module is a database containing the supplier's quality information. This database is separate from the supplier's quality system, but routines in the quality system automatically update the database whenever the data is changed. The second module is the MOLE data repository. After a request from the auditor, the data repository extracts the necessary information from the database and calculates the metrics and summary information.

The third module is the MOLE application, on the auditor's PC, which has two tasks. It provides the front end of MOLE, by which the auditor controls the system and it presents the processed data. One means of controlling the dialogue is by a query template. The auditor will have several predetermined queries requiring data from the database. For example, the trend in customer complaints will need the customer complaint records. The query template extracts these attributes from the database and transfers them to the MOLE data repository and then to the auditor. The prototype used this structure for several reasons. Discussion with potential clients showed that some may be unwilling to allow direct access to their systems, but would be prepared to have the data for MOLE automatically placed in an off-line database. Another reason was to increase the speed of the system. Further development may make these choices unnecessary.

A previous paper (Vella et al [4]) raised three technical issues facing the project. The first was how MOLE could access the information in the supplier's quality system. The solution adopted by the prototype is for the quality system to update automatically a separate database. Consequently, MOLE does not need to locate data in the quality system, preprogrammed routines pass the information to MOLE.

The second issue was how to present the information to the certification body, so that the auditors have the information they
need, but are not "swamped" by it. Using metrics addresses this issue. The metrics present the auditors with summary and trend information about the quality system, without them needing to see the detailed records (which is important for data security and confidentiality).

The third issue was the security and integrity of the data; the data the supplier provides and how the certification body analyses it. As the certification body does not have unrestricted access to the supplier's quality system, the supplier can be assured that the certification body cannot obtain confidential information. As the data MOLE uses is separate from the supplier's systems, there is little risk to the integrity of the data. Furthermore, the project partners are developing data filters, where suppliers can hold some data confidential from the system but pass summary data (via the metrics) to the certification body.

Certification bodies are aware that they are responsible for managing security of information on their premises and have evolved procedures to ensure it. Whether the certification bodies need to conceal how they analyse the information is an open question. The procedures they use for auditing suppliers are based on documented procedures, such as ISO 10011 and ISO 9001 and they can be observed during an audit! Secrecy may not be necessary or desirable.

However, other applications of MOLE, such as supplier-purchaser audits, will need confidentiality. It is in these applications where the use of filters may be of most importance.

CONCLUSION

Project MOLE has shown that it is technically feasible to develop a remote continuing audit system with most of the functionality needed for a system to connect certification bodies with software developers and other IT companies. However, there are undoubtedly other applications where the idea can be used. Large purchasers could monitor their suppliers, corporate headquarters could monitor their satellite factories and (possibly) regulatory agencies could monitor companies to ensure they were...
fulfilling their legal responsibilities (such as environmental and health and safety regulations).

In all these cases, auditing is still a manual process, but by understanding the technical and managerial issues and by applying IT solutions, the art of auditing may be improved for both the suppliers and the other stakeholders.

REFERENCES


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