



# Who Wrote This \$%&?! Program?

part II

Quality software: does it exist and how do you know?

In part I of this article we questioned the use of ISO 9000 in the software engineering process and looked at why we should audit software vendors. In part II we look at how to conduct a successful software audit and what happens if the software application is great but the company is not!

Following on from part I of this article, which appeared in the June issue of Scientific Data Management, Bob McDowall now discusses the full scope of a software audit, the role of a checklist and vendor management.

## Select the system and notify the vendor

Once the vendor has been selected, the notification of the vendor audit should be given. If the vendor accepts the audit, then a date can be fixed and plans made for its scope and content. Inform the vendor in good time that you will be requiring an audit of its processes and systems, this allows the vendor time to ensure that key people are present for your visit. If possible, give an outline timetable or schedule so that time is not wasted.

If the vendor is evasive or gives a long lag time between you and the audit, this gives you a clear message that the audit is not wanted and that the vendor has little, if any, commitment to quality. Walk away from the purchase — fast, and select another supplier.

## The scope of an audit

Having arranged the audit with the vendor, how will you do it? There are three main areas of audit possible:

- the company itself
- the quality system
- the product.

Normally a checklist is used as a guide to the audit. Any checklist will have to be customized for each different vendor and the associated product as there may be specific areas to audit. The key to determining what you need is to match what the system or product is going to do versus the impact that it will have. For a very critical system, all three areas may be audited, for a lower risk application only the company should be audited.

The coverage for each area is as follows:

**The Company:** Covers general background information, such as company history, size, previous experience with the industry you are working in, and written standards and procedures for the life cycle of the product using a defined life-cycle model. This can go further and look at the delivery and installation services, service support after purchase, training of personnel, training services and then look towards escrow services (to ensure you have access to the software if the company goes bankrupt). This type of audit can be used as the basis of a remote audit if some specific product questions are added.

This audit can also be a part of the selection process by asking the company to present an overview of itself and approaches to quality.

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The Quality Management System (QMS): The quality system of the vendor is examined through a series of questions that generally starts with the quality system, and how it is reviewed and maintained. If the vendor is certified, the standard and scope of certification should be established with a copy of the certificate. There should be written standards for developing, programming and testing the application, coupled with procedures for change control, configuration management and document review. There should be a position description for each member of staff clearly stating their responsibilities and roles. Associated with this, there should be training records covering the application of the QMS.

Evidence of continuous improvement and evolution of the quality system is very important. A rough rule of thumb is that if the quality system is static, it means it is not working and is just being used for marketing purposes.

The Product: A product audit may look at similar topics to the quality system, with the exception that the questions are more focused on a specific product or service. Some overlap with the quality-system questions may arise but this is part of the customization process. Ask here about the programming and structural testing of the product where individual units and modules of code are integrated together and tested until the final product is ready. If different

operating systems and hardware platforms are supported, ask how much development and testing your version has received compared with other units; you may be surprised to find out how little this is, especially if you are the only purchaser of this configuration. Manufacture and dispatch of the software, change control, communication of problems and software updates are all areas to examine.

The overall aim of these areas is to assess whether the company knows what it is doing and that the quality of the product you are purchasing is adequate for the purpose to which it will be put.

#### The role of a checklist

Preparation for an on-site vendor audit is essential as you will usually be time limited and you must concentrate on key areas. In my experience, a checklist is a good idea, but reiterating the views of Siri Segalstad<sup>17-19</sup> do not become a slave to the checklist. If there are concerns in critical areas, then follow them and leave some other parts of the checklist incomplete.

Should you give the vendor a copy of your checklist before arriving? There are two schools of thought on this one: yes and no! Personally, I favour being open, as nobody can fabricate a quality system and quality-system development documentation in the one or two weeks between sending the checklist and arrival on site. Therefore, I would let a

vendor have the checklist because it allows them to prepare and have documentation and people ready.

#### Conducting the audit

Planning the approach to a vendor audit is a key consideration. The use of the checklist should be combined with an overall schedule. The first decision should be the timescale for the audit: one or two days? This will be determined simply on the scale of the system and the risks that your organization runs. If you are travelling far for the audit it is not wise to have a one-day audit that has to be stopped prematurely for the audit team to catch a plane home. It is better to have a two-day audit that only lasts a day and a half. The process is outlined in Figure 1.

The audit is performed by a team with a leader who will know what to cover when they are on site. It starts with a meeting at which all involved with the audit are introduced and the scope presented. After an introduction to the company and its history, you will look at the quality management system and its application to the product. A suggested timetable for a two-day audit is shown in Table 1.

This timetable audits the QMS and then the product. However, it is important to realize that you are checking what the QMS says should be done and what was done with the product. The two should be congruent with a well-working quality system as shown in Figure 1.

It is important to remember that the aim of the audit is to gain an impression of the quality procedures of the vendor. Note that with the use of the word "impression", you are getting a snapshot of the process, not an in-depth working knowledge of the vendor's system. To help you draw conclusions as you follow the checklist you will be able to collect evidence (copies of documents, etc.), subject to confidentiality of the vendor, of the tasks involved in development of

Day 1	Audit Item
0900–0930	Introductory meeting: introductions and audit aims
0930–1100	Company overview and history
1100–1230	Quality management system
1230–1330	Lunch
1330–1430	Tour of the facility
1430–1700	Quality management system (continued)
Day 2	
0900–1230	Product quality audit
1230–1330	Lunch
1330–1430	Product quality audit (continued)
1430–1530	Auditor's internal meeting
1530–1630	Closing meeting

table 1 Outline schedule for a two-day vendor audit.

the software product that you are proposing to purchase, as you go through the audit. This evidence will help you in preparing the audit report later. Take notes as you go through the meeting. If there is more than one person involved in the audit from the purchasing organization, there is always the option to split tasks and cover ground in parallel. Alternatively, if all are involved in the audit process together, it is possible to devise roles for each before the meeting takes place. For instance, the lead auditor conducts the questioning, another can read procedures for correctness, and another can listen and ask questions as opportunities arise.

However, do not let the vendor run the audit. You are in charge. Some vendors take the opportunity to run the show and can intimidate unwary auditors. Treat such approaches with caution and dig for information and evidence that activities have been performed. Care must be exercised as even the largest software companies can have poor quality for their products.

Some items for discussion during the audit are as follows:

- Scope of Certification: this is available on the certificate held by the vendor (usually framed in a prominent position in its facilities). A copy of the certificate should always be requested. What is the scope of certification? Are all of the activities for the product or service you require included? One or two? None?
- Traceability of a requirement from the concept, through design and test, to documentation in the user guide. This is very important and essential. It is also instructive to see the quality that is built into the product for one item that is selected at random.
- During the vendor audit, care should be taken to see if there is a procedure whereby management can override the quality system. This can totally negate the quality system,

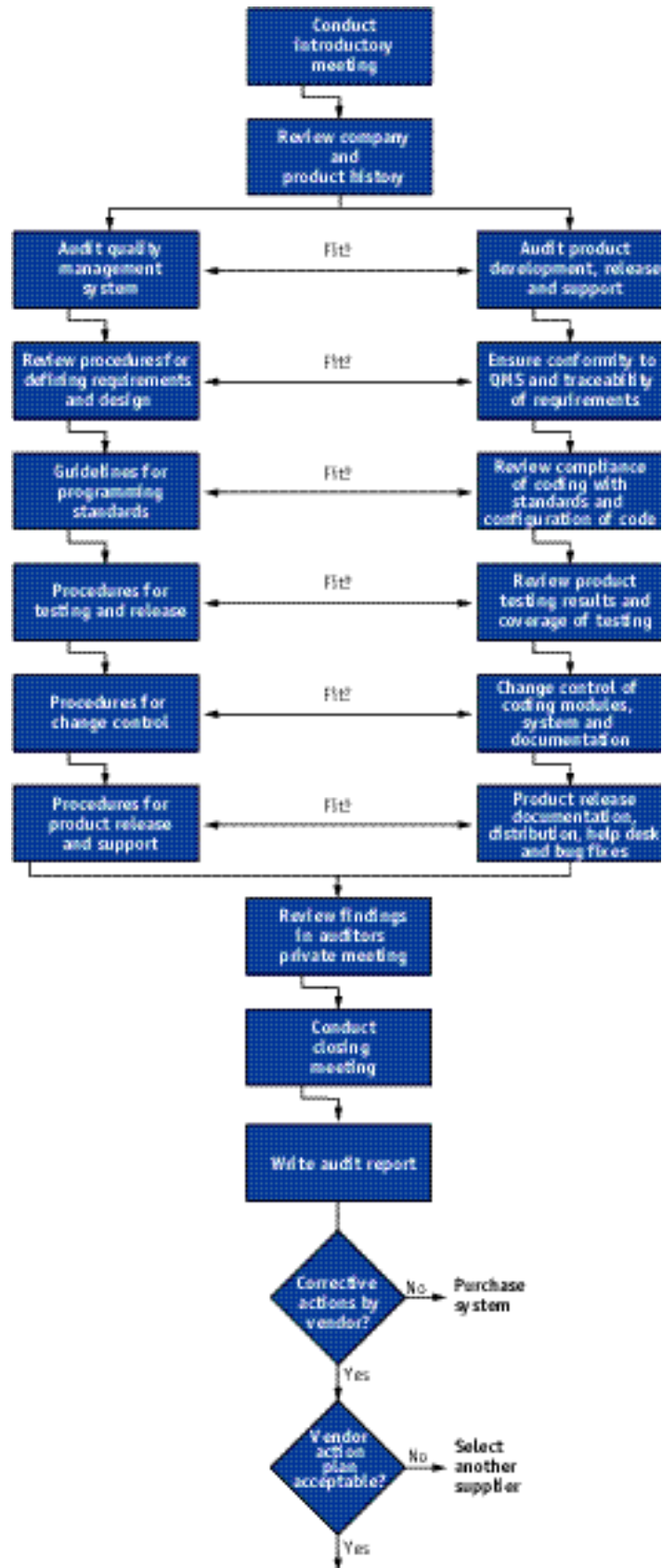


figure 1 Detailed approach of areas to cover during a vendor audit.

but will be acceptable under ISO 9001 or ISO 9000-3 because it will be a written procedure. This must be treated with extreme caution.

- Testing to fail: most tests are designed to be passed by vendors. Quality is also determined by testing to fail. If this is not done adequately when you trace a requirement through the life cycle, what is the implication for the whole product?

Once the main part of the audit is over, the team should have time to collect their thoughts, discuss their findings and draw conclusions. This is done in private by the auditing team prior to the closing meeting. At the closing meeting the conclusions of the audit team are presented and discussed with the vendor. This is an opportunity to correct any misinterpretations before the report is written and is, therefore, a two-way process.

### Prepare the report

The result of an audit is a report that summarizes the areas covered, observations made and conclusions drawn. The conclusions should state if the company has a quality attitude and that the product has enough quality built into it. Does the audit generate sufficient confidence to have the vendor as a business partner?

Follow up actions: not all audits are clear-cut. Changes may have to be made or actions addressed by the vendor. Here a follow-up audit may be required. This should also be documented using the same methods as the first and follow the same overall approach.

### A practical approach to audits

Let's be honest, a vendor audit can take time to prepare, execute and report. This applies to both the vendor and the organization. What should be the approach to a vendor audit? What is fair and reasonable and balances both the vendor's and your time?

### On-site or remote audit?

The first question to answer is, should we perform an on-site or remote audit, or both? A remote audit is essentially acquiring an overview of the company and the product's quality profile through material supplied by the vendor. This can be achieved by either asking a number of questions or requesting if an information pack on this subject exists. This approach is cost-effective for both the vendor and you as it provides a minimum level of cover for the laboratory. Some of the information you may obtain this way might be

- an overview of a vendor's quality policy
- a copy of the ISO 9000 accreditation certificate and scope (does it cover all aspects of your product or service?)
- a brochure covering the product or service you require
- documentation covering the development and testing of a product
- specific comments to your questions: a typical one may concern the availability of software source code to regulatory agencies should the need arise or an escrow agreement if the company goes bankrupt
- the financial history of the company over the past three to five years (annual reports, etc.).

### Vendor audit for a retrospective validation?

An interesting question arises during a retrospective validation of a system — what should you do about a vendor audit? Again, a reasoned judgement should be applied. Consider such questions as

- how old is the system?
- is it due for replacement within your laboratory?
- will there be any further upgrades?
- is the system obsolete?
- what is the importance of the work performed by the system?
- what is the size of the system?

A case-by-case judgement may be required, but my views are that if the system is performing important work and you will use the system through several more upgrades then an on-site vendor audit is required to satisfy the regulations. The timing of this audit does not have to be immediate, it could be timed before a major release of software for instance. This was the situation with the retrospective validation of a chromatography data system, in which the primary aim of the validation was to get the system under control, and the vendor audit was planned before the installation of the next release of software<sup>20</sup>. In contrast, a remote audit should be the approach for a system that is old, obsolete, due for replacement or will not be upgraded. Obsolete data systems were probably not developed with today's methodologies or quality standards.

### Vendor management

Occasionally there may be situations where the software application is very good, exceeding the performance of anything else on the market, whilst the company has either poor quality practices or none at all. What do you do in this case? Walk away, or work with the vendor? If there is an alternative system that you could use, then you would walk away from the company and go to another. However, if you are in a situation where there is no reasonable or workable alternative you can move from a situation of vendor audit to one of vendor management.

Vendor management (see Figure 2) is the process of working with the company to improve its internal processes. A typical situation may be where there is no formalized process for defining, designing, programming and formal testing of the application. Support and maintenance may be an ad hoc process.

In this situation, the organization may wish to work with the software vendor to document and develop the procedures and documentation.

Areas for discussion and action plans for improvement could be

- writing a requirements specification for the application, to form the baseline for design, programming and testing
- procedures for defining the modules and units that comprise the application
- defining and formalizing programming standards
- formalized approaches to testing: the procedure may allow informal testing of the module by the programmer who writes it, but formal testing starts with transfer to an independent programmer and tester
- formalized design and code walk-throughs
- definition of how to release the application
- support for the product
- change control and configuration management procedures
- registration for ISO 9001 certification with a defined scope of certification.

If you enter into a vendor management programme, it is important that the acceptance criteria for each action are defined so that there is no argument when an action is completed.

The key to a vendor management programme is how risk is managed by both the vendor and the purchasing company. Unless there is a willingness of the vendor to enter into this programme, then the purchasing company should find an alternative supplier as the long-term relationship will not be good.

### Summary

Vendor audits are essential to find out the process and quality procedures of the software development of companies that you propose to purchase from. ISO 9000 is useful but must always be treated with caution and coupled with an effective specification and selection process. Not all vendor audits will be successful, the company must either walk away and find a new supplier or be willing to manage risk and guide the development of quality procedures.

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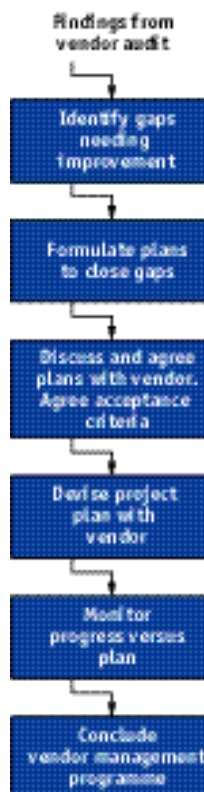


figure 2 Overview of the vendor management process.

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