Chapter 2

Audit methodologies

Although the audits conducted under the umbrella of ISO 9000 or quality management are intended to be quality audits rather than financial audits the reality has been that quality audits focus on procedures and not on quality, or to be more precise, specified outputs. Quality, cost and delivery outputs are inextricably linked and yet auditors in general do not examine costs or the extent to which products and services are delivered on time. Quality outputs are results.; results that are determined by the extent to which they meet the needs of those who require them. If the outcome fails to satisfy these needs, the output is of poor quality. If the output meets the needs it is of good quality. However, since the launch of ISO 9001, quality auditing within certification bodies and most certificated organizations has ignored the outputs and whether those for whom they are provided are satisfied. The fact that desired outputs are more effectively achieved through operating a designed process rather than unconnected procedures has still not been recognised by many auditing methodologies. The quest in most cases has been to place a 'tick in a box' against arbitrary systems, procedures and activities, leaving the question of performance unexplored and hence unchallenged. As a result, auditors fill the boxes with ticks and the organization gets the badge regardless of its actual performance. Hence the retort, "You can produce rubbish and still obtain ISO 9001 certification provided the rubbish is consistent rubbish."

The approach taken by many auditors, both internal and external has been conditioned by training and observation methods that have remained almost unchanged over decades Most auditors have been exposed to conformity auditing where the sole objective is to establish if a specific requirement has been met. However, the requirement has often not been focused on a performance result or output but has been focused on a task. To illustrate this point ISO 9001:2008 clause 4.2.3 requires changes to documents and data to be reviewed and approved. The auditor generally looks to establish that a procedure exists that requires such action and proceeded to examine changes for evidence that these have been reviewed and approved. Having found the evidence, it is assumed that the requirement has been met. One swallow does not make a summer, therefore the auditor may now look for other document changes to check that they too have been reviewed and approved. After

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gathering the evidence, the auditor makes a conformity judgement - not a performance judgement - that documents were reviewed and approved for adequacy prior to issue. The auditor probably did not search for the approval criteria or for evidence that the people concerned were competent to approve the change or for evidence that the change was indeed necessary - that it would improve performance! So how could a decision be made that the documents are in fact adequate - i.e. fit for their intended purpose? The decision is usually made from the evidence that those who approved the documents were authorized to do so. The audit revolves around documents and whether or not they are approved - not whether the information needed to perform the job is available and its integrity is assured.

It has been this longstanding pre-occupation with approval of documents and tasks that has contributed to the statement that "ISO 9000" and Quality Management systems are bureaucratic nightmares that add no real value to the organization and generate 'nit-picking' auditors.

In general, the questions any auditors ask are conditioned by the plan they have developed and the strategy taken to discover the answers. There are a number of approaches generally used in conducting internal and external quality system audits and each can be characterised by:

- ♦ the way the audit is planned (this affects what the auditor looks at and the order in which the audit is performed)
- ♦ the way check lists are produced (this affects what the auditor looks for and the questions the auditor will ask)
- ♦ the way the auditor conducts the audit (this affects the speed at which evidence is collected and its significance determined)
- ♦ the way the auditor reaches conclusions (this affects the validity of the results).

As each organization conducting audits will have evolved its own techniques there are no definitive methods but what follows illustrates the distinguishing features of three generic approaches. Only those aspects of the audit that relate to the auditor's questions are addressed. The preparation, analysis and reporting activities are omitted.

The element approach

With the element approach the auditor uses the elements of the governing Standard, eg ISO 9001:2008, as the basis for planning and conducting the

audit. An element in this context is a subsection of the Standard of which there are 28 in sections 4 through 8 of ISO 9001:2008.

Approach to planning the audit

The audit plan follows the elements of the Standard such that it commences with an examination of element 4. on Quality Management and ends with an examination of element 8.5 on Improvement . The audit schedule may not follow the elements in a numerical order as this will depend upon location and timing, but in principle, each element is matched with a person or department within the organization. When the auditor arrives in the selected department, the audit scope is limited to establishing conformity only with those requirements that are addressed by the corresponding element of the standard. Although many elements apply to each department the auditor primarily focuses on the most appropriate element for that department. The only departments in the plan are those that are perceived)by the auditor) to be within the scope of the registration. An example is shown in Table 2.1.