

## **INTERNAL AUDITS, THE AUDITOR**

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### **Introduction**

There are requirements for performing internal audits in almost all quality management standards, e.g. ISO 9001, ISO/IEC 17020 and ISO/IEC 17025. However, the requirements placed on the auditors are rather limited in all these standards. This Cook Book discusses the role of the internal auditor. ISO 19011 [4] provides guidance for internal audits and the use of internal auditors .

### **Mandate of the auditor**

Internal audits shall be planned activities. It is important that the audits are ordered by the top management of the laboratory. The internal auditor should have a clear mandate and the entire internal audit process, including the handling of non-compliances and the mandate of the internal auditor, should be clear to all parties involved. The mandate for the auditors, the handling of non-compliances and other important issues related to the internal audits should be described in a document in the management system.

One of the main differences between internal and external audits is the possibility for the internal auditor to be much more helpful in the laboratory's work with continuous improvements compared to an external auditor whose influence is much more restricted. And that option must be used by the internal auditor to make the internal audits as valuable to the organisation as possible.

### **The independence of the auditor**

Normally, an internal auditor from another department is selected to ensure the independence of an auditor. However, if the laboratory has only a few employees, auditor independence requirements can be a problem. It is allowed to use an internal auditor of the department if the laboratory is small, e.g. less than 10 employees. However, it is important that an auditor does not audit her/his own work.

When internal auditors who are not members of the organisation are used, the issue of independence is no longer relevant. For small laboratories, a combination of the organisation's internal auditors and internal auditors who are not part of the organisation (consultants) may be a good solution. For example, use a consultant for at least one of the internal audits during an accreditation cycle.

### **Confidence in the auditor**

Although the auditor acts upon a mandate from the management of the laboratory the auditor should, if possible, try not to identify the co-workers interviewed during the audit when reporting, especially if the information provided by the co-worker is negative. Otherwise, the auditor may have difficulties performing the audit to actually improve the laboratory activities.

### **The competence, training and qualification of the auditor**

The management of the laboratory can order internal audits and possibly also indicate what the internal audits need to focus on. The required competence of the internal auditor is decided by the management, who orders the audits. In other words, it is possible for an auditor to be competent for certain type of audits, but not for others.

Although the specific audit determines the required competence of the auditor, it is reasonable to make some basic demands on the auditor:

- knowledge of the requirement documents, usually ISO/IEC 17025, accreditation guidelines and in some cases ISO 9001. It may also be necessary to know documents containing requirements from voluntary and regulatory schemes,
- knowledge of the audited activities, even though a different background may lead to interesting and good findings in an audit, it is usually preferable for most internal audits to have an auditor with good knowledge of the technical area she/he audits during an accreditation cycle,
- training in auditing technique, e.g. by attending training courses, but it is also possible to be trained in auditing by following an experienced internal auditor for some audits.

### **Personal skills and attitude of the auditor**

The internal auditor should:

- not act as a police officer,
- not act as a buddy,
- be discussion partner,
- be aware that the staff being audited are usually nervous and uncomfortable in the situation,
- try to help and improve while maintaining a reasonable level of independence.

### **Advice to the auditor**

- remember to introduce yourself to all staff you interview,
- do not ask about the impossible, the normal activities of the organisation must go on,
- be aware that not all people can answer all questions,
- be active, do not let the interviewed persons lead the audit, but on the other hand you have to listen and let the interviewees finish,
- do not get stuck in papers and documents but review the actual activities of the organisation,
- keep the focus on important issues and do not lose yourself in details,
- interview many staff members,
- take clear notes the whole time; it is hard to remember what was discussed in the early morning when you write the report in the evening,
- explain non-compliances thoroughly, it is important that the non-compliances are understood and accepted by the audited organisation and the personnel,
- choose random samples, do not check everything,
- try to verify and search for evidence, do not search for faults,
- give advice and look for improvements,
- keep the time schedule, if you are late, inform the waiting persons,
- think about secrecy and independence; the personnel interviewed must be sure that the auditor does not reveal the source of criticism when it is possible, on the other hand the internal auditor responds on the mandate and the management's order,
- do not follow checklists too strictly, it is important to be able to improvise.

### **Mandate and handling of non-compliances**

It is very important to decide the mandate of the auditor before starting the audit. This is the responsibility of the top management. It is also important to emphasize that the internal auditor is not responsible for handling non-compliances. This is the responsibility of the management of the audited organisation.

### **References**

- [1] ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories
- [2] ISO 9001:2015 Quality Management Systems - Requirements
- [3] ISO/IEC 17020:2012 Requirements for the operation of various types of bodies performing inspection
- [4] ISO 19011:2018 Guidelines for auditing management systems

### **See also**

- [1] Cook Book no. 9 Internal audits
- [2] Cook Book no. 14: Internal audits, audit report