国际标准化组织　　国际认可论坛

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ISO9001 审核实践组指南

审核线索

本文件系改编自 IRCA（英国国际审核员注册协会）于 2009 年 12 月出版的第 24 期《信息》杂志中刊载的由大卫·约翰编写的题为《认识审核线索（Understanding the audit trail）》的文章。

该文可由网址 http://www.irca.org/inform/issue24/Seear.html 获得。

1. 引言

在开展专业审核时有许多重要因素。一些要求（如需要对过程进行审核）在 ISO 9000 中有明确的规定。然而，ISO 9000 标准中的术语和定义中却缺少了一个因素 — 审核线索。

审核之所以失效的最重要的原因之一是审核组未能在审核过程中对审核线索实施有效的跟踪活动。

2. 什么是审核线索?

在 ISO 9000 中没有“审核线索”定义的情况下，将普通字典中对“审核”和“线索”这两个词的解释结合起来是：“以具体样本为基础收集证据，证实一系列相互关联的过程的输出符合预期的结果的一种系统方法。”

但这个定义在实践中是什么意思呢？

虽然一些审核员已在审核中采用审核线索进行审核，但审核线索的使用并没有被普遍接受。很多审核员正是由于没有充分利用审核线索去进行审核，以至削弱了审核活动的公信力。审核员应该充分了解其审核过程的路径并据此进行审核活动，以确保过程的要求得到满足。

例如，审核员的一项活动当然将是访问企业现场。这使得审核员能够看到正在发生什么和在当时识别工件具体的订单顺序号码，从这些信息中审核员可以很容易地在销售部门识别接受该产品或服务的规范和选择的相关样本，这意味着过程可以检查，并确保销售部的工作是受控的并能满足规定的要求。审核员可以此为审核线索，并以此做为主线实施随后的审核活动。

以对采购活动的审核为例，审核员需要确定采购部门已为您抽样的产品订单购买过哪些材料或设

备。需要始终高度重视的是审核员应理解采购过程的要求，而对于采购部往往要了解采购需求和如何推动这一过程。

如果审核员不清楚采购需求和规范，那么他（她）就不能检查采购过程是否符合规定的采购要求。

- 采购要求是否符合与客户协商一致的要求？
- 采购决定是如何作出的？
- 采购要求是如何确定的？要求是否充分？
- 由谁决定采购及决定人是否被授权？
- 谁负责和以何标准选择供方？
- 评标过程怎样？
- 如何向供方告知采购要求？
- 采用的是国家标准还是国际标准？
- 控制过程的措施是什么？
- 是否有任何特殊包装交付要求？

这些仅仅是需要设法解决的问题的一部分，具体应遵循 ISO 9001 条款的要求。

3. 正确的样本

审核开始时，审核员应选定样本，确定审核路径和应用过程控制。至关重要的是，样品应该是相互联系且源自于同一个审核线索。审核员往往会在过程的不同阶段频繁地采集样本，而与最初选择的样本不相关，这意味着，审核员将无法验证该过程的工作。他只能以检查该过程特定文件是否正确填写，在有关文件都妥当保存的情况下，才能验证过程的符合性。

程序、表格、清单等等都是用来确保有效地管理和控制过程，重要的是审核员要花时间来了解在过程中，他们需要审核什么要求。

如果审核员在审核中不花时间去了解企业的产品或服务规范（包括法律及法规要求），第二或第三方审核员是不可能对一个组织进行审核的。正是这种专业的审核方法，使审核员得以确定在这一过程中存在任何弱点，并决定一个组织是否能满足规定的要求。审核线索方法适用于任何审核（无论是内部审核，第二方审核或第三方审核）。

（HXQC 宋治民编译，仅供参考）

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ISO 9001 Auditing Practices Group

Guidance on:

Audit Trail

The following paper by David John Seer is adapted from an article in IRCA's **INform** journal (Issue No.24, December 2009, http://www.irca.org/inform/issue24/Seear.html)

1. Introduction

There are numerous of important elements in carrying out a professional audit. Some requirements, such as the need to audit the process, are defined in ISO 9000. There is, however, one element of auditing that is missing in the terms and definitions in ISO 9000 – the ***audit trail***.

The failure to carry out a process audit following an audit trail is the single most important reason why audits are not effective.

2. What is an audit trail?

In the absence of a definition from ISO 9000, a standard dictionary definition for 'audit' and 'trail' arrives at the following:

A systematic approach to collecting evidence based on specific samples, that the output of a series of inter-related processes meets expected outcomes.

But what does this mean in practice?

Although applied by some auditors, the use of an audit trail is by no means universally accepted. It is the failure to ensure all audits employ process audits following an audit trail that undermines their credibility. Auditors should understand the path of the process that they are auditing and perform the audit accordingly, ensuring that the requirements of the process are being met.

For example, as a matter of course auditors will visit the shop floor. This enables the auditor to see what is taking place and to identify the specific order numbers of jobs that are going through at that time. From this information it is easy to identify in the sales department the agreed specification for that product or service and select relevant samples to be chosen. This means the process can be checked to ensure that what takes place is controlled and will meet the required specification. From here, the audit trail is picked up and followed through.

Using the audit of a purchasing activity as an example, you need to identify what material or equipment has been purchased for your sample order. It is always important to understand what drives the process. In this case, it is normally the requisition, which defines what is wanted.

If the auditor does not understand the specification, then he or she cannot check if the process being followed meets the requirements of the requisition.

- what does the requisition require – does this comply with the agreed specification?
- how is the decision to purchase made?
- how is the specification decided? Is it adequate?
- who decides what is required and do they have the authority?
- who chooses the supplier and by what criteria?
- what is the process for bid evaluation?
- how is the specification advised to the supplier?
- are national or international standards used?
- what controls the process?
- are there any special packing delivery requirements?

These are just some of the issues that need to be addressed, many of which follow the clauses of ISO 9001.

3. Correct samples

The starting point for the audit is to use the chosen samples and identify the process path and the controls that were applied. It is vital that the samples are linked and come from the same trail. Too frequently, audit samples are taken at different stages of the process and are not related or linked to the initial sample chosen, which means that an auditor is unable to verify that the process is working. He will only be able to check if that particular document is filled in correctly.

Procedures, forms, checklists and so on, all ensure that a process is managed and controlled effectively. It is essential that auditors take the time to understand what is required from the process they are auditing.

It is impossible for a second- or third-party auditor to carry out an audit of an organization if the auditor does not take the time to understand the specification of its product or service, including statutory and regulatory requirements. It is this professional approach to auditing that allows the auditor to identify any weaknesses in the process and decide if an organization is capable of meeting the specified requirements. The audit trail approach applies to any audit be it an internal, second- or third-party audit.