AAPG 和 APG 指南简介

AAPG 和 APG 分别是 Accreditation Auditing Practices Group——“认可评审实践工作组”和 ISO 9001 Auditing Practices Group——“ISO 9001 审核实践工作组”的英文缩写。这两个工作组由国际认可论坛（IAF）和国际标准化组织质量管理与质量保证技术委员会（ISO/TC176）共同设立，它们的共同任务是组织国际认证认可领域的专家，对如何提高 ISO 9001 质量管理体系审核与认证及其认可的有效性、从根本上改进认证认可的可信性和质量进行讨论和研究。工作组的研究成果，即相关专家对 ISO 9001 认证和认可实践具体问题的指南性意见，以 AAPG 或 APG“白皮书”的形式发布，供认证机构及其审核员、认可机构及其评审员、建立和实施 ISO 9001 质量管理体系的组织、咨询人员以及所有对质量管理、认证和认可感兴趣的人士参考。

从 2004 年到 2008 年 2 月底，AAPG 共发布了 10 份指南白皮书，范围涉及认可评审员能力、基于过程方法的评审、认证机构公正性委员会、见证评审、认可范围、审核时间等问题；APG 共发布了 34 份指南白皮书，以 ISO 9001 相关条款的理解、实施和审核为出发点，对质量管理体系审核和认证的各种具体问题进行了阐述。APG 将继续识别和研究 QMS 审核和认证的相关问题，并计划将工作范围扩展到 EMS 及其他管理体系领域。

中国合格评定国家认可委员会（CNAS）作为 IAF 成员，自 2005 年以来，积极参加了 AAPG、APG 的会议和讨论研究，并参与起草了部分白皮书。为了使我国认证认可工作者更好地了解国际认证认可领域的技术研究动态，有效利用相关成果来改进认证认可有效性，CNAS 组织认可评审员和部分认证机构专家对 AAPG 和 APG 已发布的白皮书共 44 份进行了编译，并与英文原文共同编辑成册，供大家参考。由于时间和水平有限，译文中难免有疏漏和欠妥当之处，敬请读者理解和原谅，并积极向 CNAS 提出宝贵意见（请将书面意见发至 renqy@cnas.org.cn）。

AAPG、APG 指南白皮书的参考译文还将刊登在 CNAS 网站上。AAPG、APG 白皮书的英文原文和两个工作组的详细情况，可从 AAPG、APG 网页上获取:

www.iso.org/tc176/AccreditationAuditingPracticesGroup

www.iso.org/tc176/ISO9001AuditingPracticesGroup

CNAS 将随时根据读者反馈意见，对现有的参考译文进行修改和完善，并在 CNAS 网站上更新；CNAS 还将及时跟踪和翻译 AAPG 和 APG 新发布的指南白皮书，并在 CNAS 网站上发布，敬请关注。

请读者注意：AAPG 和 APG 指南白皮书只代表工作组成员专家对相关问题的理解和意见，不是 IAF、ISO/TC176 或 ISO/CASCO 的强制性要求，也未经这些组织正式审查和确认，仅供读者参考。参考译文中多处使用了“准则”、“要求”等名词，或“应”、“应当”、“宜”、“不宜”、“必须”等情态动词，这些用语不应被理解为代表 CNAS 的认可要求。

在此，谨对参与 AAPG、APG 指南白皮书编译、审校工作的中国新时代认证中心、广东赛宝认证中心、中国电子技术标准化研究所(信息产业部电子工业标准化研究所）认证中心、华信技术检验有限公司（排名不分先后）和北京经纬方正技术咨询有限责任公司等单位表示感谢。

中国合格评定国家认可委员会

二〇〇八年三月

目　录

注：审核员/评审员道德和行为准则（Auditor Code of Conduct and Ethics），同时作为 AAPG 和 APG 指导性文件。

日期：2005 年 7 月 30 日

认可评审实践工作组指南

认可机构对认证机构审核的见证

1. 介绍

认可机构见证认证机构对其客户的审核，具有以下价值:

- 在现场验证认证机构的方案和程序的有效性(特别是在委派有能力的审核组方面）。
- 对认证机构审核员进行认证审核、监督审核或在认证审核的情况进行观察，以评价他们是否:
  - 符合认证机构的程序;
  - 充分地遵循了以下文件的要求或指南:
    - ISO/IEC导则62;
    - 相关的IAF指南;
    - ISO 19011:2002;

    及，适用时，任何相关的行业性要求。

这将使认可机构能够确定认证机构是否有效地控制了认证决定和认证过程，从而能够对认证机构实施经认可的认证的能力进行评价。

2. 审核前的准备

为了能够进行见证评审，认可机构将需要与已认可的和申请认可的认证机构有正式的安排。这些安排应当确保认可机构有权在认为必要时对认证机构的审核实施见证，并确保认证机构与其客户有相应的安排，以允许上述见证得以实施。

这些安排可能需要涉及诸如保密性（认可机构与认证机构之间、认可机构与认证机构的客户之间）此类的问题。

认可机构在决定是否需要对认证机构的审核实施见证时，应当考虑诸如下列的因素:

- 认证机构总体上的绩效;
- 与认证机构业务涉及的工业和服务业领域相关联的风险;
- 来自利益相关方的反馈;
- 认证机构内部审核的结果，等等。

认可机构应当确保见证评审的成本经济合理，并尽可能减少对认证机构及其客户的影响。

在策划见证评审时，认可机构应当确保有认证机构的相关信息。这些信息应当包括以下方面（适用时）的详细情况:

- 认证机构的组织结构;
- 认证机构的质量管理体系;
- 认证机构的运作程序;
- 对认证机构以往评审的结果;
- 向认证机构和认可机构提出的投诉。

此外，在对一个特定的审核（一个特定的认证机构对其一个特定的客户进行的审核）进行见证时，认可机构应当确保有以下方面的详细情况:

- 认证机构的审核计划;
- 认证机构审核组的背景信息;
- 认证机构客户及其质量管理体系的历史情况;
- 关于审核的后勤安排信息（例如审核的时间和地点等）。

认可机构应当有选择和委派自己的评审员的正式过程。认可机构只应当委派有能力的评审员或评审组对认证机构的审核实施见证。认可机构的评审员应当具有:

- 对认证机构客户的业务、过程和产品的适当的知识;

- 对该客户的产品必须符合的法规类别的基本理解;
- 对审核实施见证和收集任何必要信息的能力。

认可机构应当在实施见证前提前通知认证机构:

- 认可机构对其审核实施见证的目标;
- 见证评审的过程;
- 认可机构的反馈和报告过程。

认可机构应与认证机构就见证评审员在审核中的角色和作用达成一致，并就如何向认证机构的客户进行介绍和说明达成一致。

认可机构应当使所有利益相关方明白，认可机构的评审员在见证认证机构的审核时，不是在对认证机构客户的质量管理体系直接进行审核，进行这一审核完全是认证机构的职责和义务。

3. 审核过程中

在对认证机构的审核进行见证时，认可机构评审员应当仅作为观察员来参与审核，不应当干预认证机构对其客户的审核。此外，认可机构评审员应当确保自己不以任何方式来影响认证机构审核的结果。

然而，这并不妨碍认可机构评审员通过在审核中间安排简要通报，或寻求澄清和进一步的信息等方式，来积极地参与过程。澄清、信息沟通、简要通报等应当在策划好的休息时间或单独的会议中进行，这样更好一些。然而，可能也有必要在临时决定的休息或会议中进行这些活动。进行这些活动时，认证机构的客户应当不在场，以确保认可机构对认证机构的相关信息保密。

注: 见证评审中收集的任何信息都是保密的，认可机构的评审员和工作人员必须对其予以保密。

认可机构评审员应当避免在审核进行中向认证机构或其客户提供任何意见。

为了使见证评审的价值最大，认可机构评审员应当试图覆盖认证机构的整个现场审核过程。

认可机构评审员应当使认证机构的客户不认为认可机构评审员的在场和见证活动是一种干扰，而认为是一种正面的活动。

4. 反馈和报告结果

认可机构评审员应当仅在审核完成后提供对认证机构表现的反馈意见。在可能时，应当策划在审核结束时，在认证机构客户的场所提供这种反馈意见（认证机构的客户应当不在场）。

认可机构评审员应当仅在收到并审查了认证机构自己的审核报告后，再编写见证评审的报告。

见证评审报告应当避免重复描述认证机构客户QMS绩效的细节以及认证机构审核组提出的审核发现，因为这些内容应当已经包括在认证机构的报告中。

但是，可能会有这样的情况，在见证过程中对某一情况提出了观察意见，而认证机构审核组没有报告这一情况（例如认证机构客户与法规要求相抵触，或认证机构客户的QMS没有正确的符合法规要求）。认可机构评审员应当在审核后的反馈过程中，向认证机构告知上述观察意见，并应当将其作为不符合记入见证评审报告。

如果认可机构的报告包括不符合项，应当要求认证机构管理层采取行动来处理相应的问题。

相似的，如果观察意见清晰表明认证机构对客户QMS的审核存在严重不足，使人对认证机构认证过程的有效性产生怀疑（特别是在监督或再认证审核中），那么这一问题应当在认可机构的报告中进行正确的记录，得到认证机构管理层的正确处理，并应当提交认可机构做进一步的考虑和处置。

日期：2005 年 7 月 30 日

认可评审实践工作组指南

基于“过程方法”的认可评审

1. 介绍

在认可评审中使用过程方法将增加认可活动的价值，因为被评审的机构自身通常也采用过程方法。

虽然在认可评审过程中采用过程方法并不是 ISO/IEC 17011 的直接要求，但来自认证机构的反馈显示认证机构希望认可评审员理解并能够在评审中应用过程方法。

ISO/IEC 17021 鼓励认证机构运作一个（与 ISO 9001:2000 的原则一致的）正式的管理体系，因此该标准将提升过程方法的价值和对过程方法的需求。

过程方法有助于认可评审员去关注利益相关方的需求和期望，并为持续改进提供了基础。

过程方法的基础是识别与认证机构活动相关的关键过程，以及这些过程的正确管理和控制。

更多关于过程方法的信息可以从公认的信息来源获得，例如 ISO 9000:2000 质量管理体系 基础和词汇，以及 ISO 9000 介绍和支持包：过程方法的概念和适用——指南 (ISO/TC 176/SC 2/N544, 可从 http://www.iso.org/tc176/sc2 下载)。

2. 认证机构的目标

以一致的方式对客户 QMS 是否符合适用要求进行证明，是认证机构过程所要实现的终极目标。认可评审员宜随时随地关注这一总体目标。

为实现这一目标，认证机构所需要的典型过程是:

最高管理层过程

- 战略策划;
- 管理评审（根据内部审核);
- 申、投诉管理。

资源管理过程

- 信息管理;
- 人员（内部员工，审核员）资格评定和监视;
- 分包商管理（外包过程）;
- 后勤。

产品实现过程

- 编制报价书;
- 合同评审;
- 策划认证方案;
- 确定审核的时间安排;
- 配备审核组;
- 报告审核结果;
- 认证决定;
- 收取认证费用;
- 认证的保持;
- 认证的暂停和撤销。

测量、分析和改进过程

- 内部审核;
- 绩效分析;
- 监视客户及其他利益相关方的满意度，包括关注获证产品和服务的最终用户;

- 上述主要过程所包括的其他测量和监视活动。

3. 认可机构的应用

认可机构宜确保其所有评审员都接受了关于 ISO 9001:2000 要求的充分的培训，特别是在过程方法方面，因为被评审的机构在见证评审时将使用过程方法。

对于上述过程，认可评审员宜考虑下列基本方面:

- 认证机构是否已识别了过程（包括过程目标）并将其形成文件？及确定并委派了相关的职责？
- 是否确定并配置了相关的资源和信息？
- 是否有方法来监视和（或）测量及分析每个过程，包括适当的记录，是否已确认了它们的有效性？
- 是否正确处理了认证机构运作有效性的持续改进问题？

认可评审员必须意识到，不同认证机构对过程方法的应用可能不同，这取决于机构及其活动的规模和复杂程度。

4. 示例——认可机构在基于过程的评审中要解决的问题

注: 下列问题本身隐含着对适用标准和指南的条款的引用。这些问题可以与正式的认可要求相对照。

原则上讲，下列问题适用于任何类型的评审过程。

过程特性

- 认证机构质量管理体系需要哪些过程（参见上面的认真机构典型过程清单）？
- 这些过程中有外包的吗？
- 每个过程的输入/输出是什么？这些输入/输出符合认可要求吗？
- 这些过程的“顾客”是谁？
- 这些顾客的要求是什么？
- 这些过程的“所有者”是谁？

- 这些所有者有能力进行工作吗?
- 过程参与者的能力是如何确定、评价和保持?

准则和方法

- 预期的过程结果的特性是什么？这些结果符合认可要求吗?
- 监视、测量和分析的准则是什么?
- 这些准则是怎样被纳入过程策划中的?
- 是否适当考虑了经营绩效的问题?
- 对认证机构的公正性和诚信性有影响吗?
- 用什么方法来收集数据?

资源

- 过程需要哪些资源？这些资源适宜吗？符合认可要求吗?
- 沟通渠道是什么?
- 如何提供关于过程的外部和内部信息?

反馈

- 需要收集什么数据?
- 需要保持什么记录?

测量、监视和分析

- 如何监视过程的绩效（过程能力，顾客满意度）?
- 采用什么测量指标?
- 如何分析收集到的数据（统计技术）?
- 如何来考虑分析的结果?

日期：2005 年 7 月 30 日

认可评审实践工作组指南

质量管理体系认证机构审核员和审核组能力的评审

1. 引言

按照 ISO/IEC 指南 62 和相关 IAF 指南文件的要求，认证机构必须建立体系，以规定、评价、证实和保持参与认证过程的人员的能力。认可机构评审组在推荐认可前，宜获取证实认证机构满足上述要求的证据。

对认证机构审核员能力的评审包括以下两个方面:

a) 认证机构是否对审核员的能力进行了评价，包括对每个审核员的资质（如教育、培训和经历）进行评审;

b) 确定认证机构是否针对每次特定的审核，用合格的审核员来组成有能力的审核组。

2. 审核员资质和能力的评审

ISO 19011:2002 对“能力”的定义是: 经证实的个人素质、知识和技能。ISO 19011:2002 第 7 条进一步说明: 对于 QMS 审核员，能力实际上是建立在个人素质、通用的知识与技能以及特定知识与技能的基础上。(注 1: ISO 19011:2002 的表 1 与能力没有什么关系，不宜依据或参照该表来确定能力要求)

导则和指南并没有要求通过人员认证资格来证明认证机构审核员具备能力，而且人员认证资格本身也不足以证明审核员具备能力。证实审核员是否具备能力的责任完全在于认证机构自己。认可评审员不能光看人员认证证书，还要对认证机构批准审核员能力的依据、审核员的认证活动以及授予认证的理由等进行评价，以确定审核员是否令人满意。

认证机构应当能够证明审核员经过了评价和测试，以及审核员的能力已得到了正确地证实。

(注 2: 如果审核员以前当过审核组长[19011:2002 所定义的审核组长]，这并不能保证该审核员就有能力对另一个组织进行审核。审核组长的身份不宜被认为终身有效)

a) 个人素质

认证机构的审核员记录宜表明认证机构对每个审核员的个人素质进行了评价。

这类评价可以采取多种方式，例如，从自我评价和简单的观察，到更为复杂的方法，比如心理分析。重要的是，所选用的评价方法能够正确地发现被评价人的不足。评价后，认证机构宜对所遇到的问题予以纠正（通过相关审核员的进一步发展），或者仅派相关审核员从事不会对他和审核造成损害的审核，以控制和减轻所遇到的问题。

b) 通用的知识与技能

通用知识与技能的最重要方面与管理体系的原则和实践有关。审核员对认证标准有着正确的理解也很重要，这关系到审核发现是否正确。

审核员可以通过成功地完成正式的培训课程和（或）认证机构的特定培训项目（例如可以通过角色扮演或在别人指导或监督下进行审核来发展审核技能），来获得审核原则、程序和技术方面的知识。

认证机构宜对有效的 QMS 审核所需的有关质量方法与技术的知识与技能进行分级。这些宜包括现代质量管理工具及其应用。

宜有证据表明认证机构审核员已有效地获取了能力所要求的知识，而且他们的表现已经过证实和考核，并已被接受，而不是仅凭审核员完成或参加某个培训课程的记录。

认证机构审核员的知识和技能应当通过持续的职业发展来得到保持和更新。

c) 过程和产品

过程和产品方面的能力是审核员最难获取的知识和技能，也是认证机构最难于应用的。

经验表明，过时的或已失效的工作经验的价值经常是有限的（特别是当审核员声称自己通过咨询活动获得了产品和过程方面的知识时，认证机构需要谨慎对待）。

认可评审员宜确定认证机构已认识到，审核员将面对各个行业里特定的术语和行话，过程和产品（包括服务）的技术特性，还经常要面对行业里独特的特定过程和做法。

不管认证机构采用何种方式，我们都希望他已经规定了在确定审核组所需能力时要满足的关于特定产品的知识与技能。

有些行业的产品和过程比较简单明了，但有的行业的产品和过程可能很复杂（特别是在像食品、航空、农业、金融和教育这样的行业。又比如像设计和开发这样的过程要求审核员具备特定的能力）。

认可评审员宜验证认证机构在委派审核员时，已正确考虑了认证机构承担的与产品/过程或特定行业相关联的风险。认证机构针对高风险的情况要求审核组必须包括有能力的技术专家，这可能是好的做法。如果是低风险的情况，认证机构可能让不具备特定产品和过程的知识与技能的审核员经过专业引导后，单独进行审核。

在某些情况下，一套基于比较宽泛的专业资格（例如机械工程，电器工程，工业工程或冶金）的简单机制可能就足够了。在其他情况下，考虑更详细的行业划分（例如软件－网络专家，农业生态专家、食品工程师、营养师、卫生师、材料科学家等）可能更为适宜。

认证机构审核员有可能达到在其主要专业以外的技术领域进行有效审核所需的知识与技能水平。这可以通过诸如在有能力的审核员的指导下进行审核这样的方法。

在复评和监督审核中，审核员应具备的关于过程与产品的知识与技能宜与初次审核相同。

d）组织的规模

审核一个大型多场所组织和审核中小企业（在中小企业中，一个员工往往要参与多个过程，同时肩负多项工作和职能）所需的知识与技能是不同的，这一点为人所公认。熟悉中小企业的审核员不一定有能力审核大型组织，反之亦然。另一方面，还要考虑由于组织规模不同而产生的企业文化差异，这一点也很重要。

认证机构宜避免委派不具备与拟审核组织规模相适应的知识与技能的审核员。

认可评审员宜获取证据，来证实审核员通过适当的方法获得了在不同情况下进行有效审核所需的知识与技能。这些方法包括（但不限于）通过培训、工作经历及实习审核经历来了解相关的组织。

e）文化和语言

认证机构经常需要派审核员到其他国家的组织进行审核。语言和文化方面的差异可能妨碍有效的审核。

认证机构宜记录审核员的语言能力，以及他们曾工作过的国家。

如果认证机构无法找到掌握拟审核客户的语言和了解其文化的审核员，那么宜确保有翻译人员在审核中协助审核员。值得推崇的做法是，此类翻译人员宜独立于受审核的客户。另外，在审核前对审核员进行文化方面的指导或培训，将是有用的。

认可评审员宜检查认证机构在审核员委派过程中是否有效处理了上述问题，以及在需要配备翻译人员时，是否在审核策划和准备过程中有效处理了上述问题。

f）法律和法规要求

认证机构审核员宜了解适用于拟审核的 QMS 的法律和法规。认证机构宜确保审核员了解这些法律和法规，并且在审核中适当的关注这些法律和法规。

3. 能力要求的评价

对于每次审核，认证机构宜确定拟审核组织的大体情况（体现为所建议的认证范围）。

然后，认证机构宜根据组织的情况，基于上述第 2 部分的准则，确定对实施该审核的审核员和（或）审核组的能力要求，并将这些要求形成文件。

认证机构确定的能力准则至少需要确保审核员在审核中有令人满意的表现，审核有充分的深度和一致性，并能提供增值。

4. 用有能力的审核员组成审核组

对于每次审核，认证机构宜能够证实他（从现有的审核员库中）选择了有能力的审核员或审核组，符合为审核确定的能力要求（参见上面第 3 部分）。

但是，认证机构可能有必要为审核组配备特定的技术专家，以使审核组的能力与组织的情况相匹配。认可评审员宜考虑这一点。

认证机构审核员库中的一些审核员不具有所需要的所有知识和技能，认可评审员宜确定认证机构在审核员委派过程中设有防范措施，以确保这些审核员不进行超出自己能力的活动。

日期：2006 年 5 月 15 日

认可评审实践工作组指南
ISO 9001 审核实践组指南

审核员/评审员道德和行为准则

1. 介绍

毫无疑问，人们经常认为审核员/评审员非常有权力，并且享有特权。

本文件的指南针对那些审核员/评审员需要注意的方面，如果忽视这些方面，可能会损害审核员/评审员的行为操守。如果审核员/评审员与其雇主的合同条款中没有规定审核员/评审员的行为准则，那么本文件尤其有用。本文件还提供了道德准则的一个范例。

2. 基本说明

为发扬高尚的道德行为，审核员/评审员**应**:

1) 在履行其职责时，完全从雇主及其客户的最佳利益出发行事;
2) 保持诚实、正确、公平和负责的职业品行;
3) 不错误描述自己的资格、能力或经历，也不承担超出自己能力的任务;
4) 以保密和隐私的方式对待在认证或认可活动中获取的与特定的组织、机构或人员有关的信息，除非该组织、机构（适用时，还包括组织或机构的顾客）或人员书面授权其披露有关信息，并且
   - 除那些为了认可或认证过程的合法目的而需要了解这些信息的人外，不与任何人谈论这些信息;
   - 在审核/评审过程之中或之后不透露审核/评审发现的细节;
5) 以保密和隐私的方式对待所获取的有关上述实体活动的、可能包括（但不限于）以下方面的信息:

- 与该实体的活动有关的、明确标识为“机密”的任何装置、图表、书面材料或其他有形或无形的信息;
- 因其内容和（或）背景而被识别为隐私的任何装置、图表、书面材料或其他有形或无形的信息;

6) 以保密和隐私的方式对待所有可能被上述实体视为“机密”的信息，并承认有些信息虽未被明确识别为机密信息，但实际上应予保密。

7) 不有意传播可能损害认证或认可的过程或决定的诚信性的错误或误导性信息。

8) 在来自雇主或受审核/评审方的不利压力下，仍能够以专业的方式行事。

3. 道德准则范例

为维护和发扬合格评定工作的荣誉、尊严和诚信，保持高尚的道德行为标准，我承认我将:

a) 基本准则

1) 诚实公正，致力于为雇主、客户、公众和我的确定的组织服务。

2) 努力提高审核职业的能力和声望。

3) 用我的知识和技能为人类造福，提高产品和服务对公众使用的安全性和可靠性。

4) 诚挚地帮助我的组织开展工作。

b) 与公众的关系

5) 致力于积极地促进公众了解每个组织及其成员的工作中与公众福利有关的方面。

6) 在解释我的工作及其价值时保持尊严和谦虚。

7) 在我可能发布的任何公共声明中，首先说明我是代表谁发布该声明的。

c) 与组织、雇主和客户的关系

8) 作为每个组织、雇主和（或）客户的受托人行事。

9) 向每个组织、雇主或客户告知任何可能影响我的判断或损害我服务的公正性的商业联系、利益或从属关系。

10) 未经现在或以前的组织、雇员或客户正当同意，不透露有关他们的机密性业务或技术过程的信息。

11) 对于同一项服务，仅从一方取得报酬，如果从一方以上取得报酬，那么要事先征得所有各方的同意。如果受雇，我仅在征得雇主同意后，再从事另外的雇佣工作或咨询活动。

d) 与同行的关系（适用时）

12) 尊重他人工作的成果和价值。

13) 努力帮助我所雇佣或管理的人员的职业发展和进步。

14) 不与他人做不公平的竞争，与我的同事和业务伙伴建立友谊和信任。

15) 尊重同行的意见，确保审核/评审组内诚实、公开的氛围。

16) 以公开和职业的方式对同行不道德的行为做出反应。

日期：2006 年 12 月 8 日

认可评审实践工作组指南

认可评审员和评审组能力准则

本文件的指南针对如何确定和评价认可评审员和认可评审组的能力，以改进认可过程的有效性，并增强不同认可机构所用方法的一致性。

1. 能力准则

通常来说，认可评审员应当:

- 熟悉相关的认可及合格评定标准，及认可机构的认可程序;
- 接受过适宜的评审员职业培训;
- 很好地了解和理解不同的评审方法;
- 具有评审所需的适宜的经验和技能。

ISO 19011 对如何应用上述准则提供了指南。

认可评审员应当能够使用基于过程的评审，应当能够理解受评审机构的过程，并将这些过程与相关标准和导则的要求联系起来。此外，认可评审员应当有能力将不符合项追溯到认证机构的过程或管理体系（见 AAPG 指南《基于“过程方法”的认可评审》）。

认可机构应确定实施认可评审所需能力的准则，认可评审包括所要求的办公室评审和见证活动。主任评审员、评审员和实习评审员可以有不同的准则。该准则应基于 ISO/IEC 17011，并应当由认可机构中制定政策的部门或机构的批准。

能力准则可以采用基本（通用）要求和专用要求（针对特定的认可方案和行业以及其他特定方面）的形式。

下列给出的能力准则中，强调了认可机构在为特定评审选择评审员和评审组时，应当考虑的因素:

基本（通用）要求

a）程序和标准

- 关于认可机构程序的知识，
- 关于认可机构标准（ISO/IEC 17011）和适用于拟评审的合格评定机构的标准（ISO/IEC 17021，ISO/IEC 指南 65，ISO/IEC 17024，ISO/IEC 17020）以及相关的 IAF 指南文件的知识。
- 关于 ISO 19011 的知识。

b) 个人素质（见 ISO 19011）

认可机构应当采用不同方法来评价每个评审员的个人素质。评价结果应当用于指派评审员执行特定评审或评审组的委派。

c) 通用的知识和技能

- 理解合格评定机构业务过程的能力，以及对这些过程实施评审的能力；
- 做出判断的能力。

特定要求

d) 在与认可方案/行业相关的要求和法规要求方面：

- 对于管理体系认证认可方案，评审员应当有管理体系标准的知识；
- 理解/熟悉与经认可的管理体系认证所覆盖的经济和（或）社会活动相关的产品、过程和技术；
- 对于产品认证认可方案，评审员应当有产品标准、生产技术、产品使用和相关问题的知识（注：对于产品、过程、设备设施、设计等的检查机构的认可评审，适用经过适当调整后得到的相似要求）；
- 对于人员认证认可方案，评审员应当有不同职业的适用标准、技术诀窍和技能的知识；
- 理解和掌握相关的工具和方法，以便能够确定合格评定机构是否正确地管理了适用的法规要求。

评审员/评审组应当从下列方面获得上述知识:

* 相关行业领域的直接工作经历;
* 相关领域的教育、研究和标准化活动;
* 咨询和审核活动; 或
* 上述方面的组合。

如果评审员或评审组没有足够的上述知识，则应当由技术专家提供支持。

e) 需要评审的合格评定机构的特性:

在选择评审员/评审组时，应当考虑这些特性，例如合格评定机构的规模、业务部门的数量、开展业务的国家等等。

f) 文化和语言

在策划评审和选择评审员/评审组时，应当认真考虑这些方面。这些方面对于跨国认可评审（包括办公室评审和见证评审）来说尤为重要。

至于对认可评审组的要求，认可机构应当确保评审组整体上具有进行特定评审所需的能力（参考上述 a) 到 f)），包括可能识别出的特定技术能力。如前所述，在评审员不具备特定的专业技术能力时，需要为评审组配备专家。

2. 资格评定过程

评审员/专家的资格评定过程应当包括能力的确认和持续保持所要求的初次选择、培训、继续培训和定期评价。认可机构需要:

- 选择评审员和专家（根据教育背景、知识、经验和技能）;
- 通过适宜的培训课程或等效方式，对评审员和专家进行认可规则、认可方法、认可程序、认可准则及任何相关规定的培训;
- 通过适宜的方法 (见 ISO 19011)，对评审员和专家进行持续地监视和评价。

日期：2007 年 1 月 19 日

认可评审实践工作组指南

对认可范围的评审

本文件提供的指南针对认可机构在向合格评定机构（CAB）授予特定的认可范围时，应当怎样对 CAB 的能力进行评审。本文件的指南旨在促进不同认可机构采用有效和一致的评审方法，减少不一致。

认可过程的一个关键目的是确保获得认可的 CAB 在其认可范围内能够正确的运作。认可范围是指 CAB 申请认可或已认可的合格评定活动的类型和领域 (注：认可范围的正式定义见 ISO/IEC 17011)。

为此而进行的认可评审以下面两类基础性评价为基础:

- 分析 CAB 的文件，以及
- 观察 CAB 的特定行为。

文件分析至少应当包括:

- 审查 CAB 对审核员能力准则和选派有能力的审核组的文件规定，包括能力分析的实施记录;
- 审查对认可范围内的不同合格评定活动规定具体要求的程序、指南、检查表、工作指导书等（如有时）;
- 审查合同评审时依据的程序、进行合同评审的人员、认证资源的配置和认证决定等;
- 分析 CAB 定期对上述准则进行维护和复审的过程记录;
- 检查证明 CAB 审核员能力的形成文件的证据。

文件审查应当评价 CAB 是否是在分析特定工作所需能力的基础上，规定对审核员和审核组的能力、选择的准则。

CAB 的审核员或审核组、资格评价过程应当基于已确定的能力准则，并至少应当考虑下列内容:

- 教育水平和研究经验;
- 与认可范围有关的行业领域的工作经验,以便审核员能够理解相关的过程和产品特性以及适用的法规要求;
- 在直接工作经验以外,或作为直接工作经验的补充,通过审核活动获得的经证实的知识和技能,但这些审核应当是在专业审核员/技术专家的指导下进行的,而且有支持性证据(例如认证档案、记录和评价报告)。

文件审查还应当评价 CAB 为每个审核员的能力(由审核员的职业经历显示)提供证明的文件是否与 CAB 规定的能力要求相一致。

此外,文件审查还应当确定 CAB 是否制定了专门的指南(例如专门的程序或作业指导书),以帮助审核组在认可范围内的专门领域中进行审核,同时还应当确定这些指南是否有效地加强了审核组的能力。这些指南的特性(形式和内容)应当以 CAB 对相关风险因素的评估为基础。

对 CAB 在实际操作中的**行为的观察**,应当以下列为目标:

- 确认 CAB 建立的确保审核员能力和委派有能力的审核组的程序与准则得到了有效和一致的实施;
- 确定在审核中(包括实施审核和报告审核结果)是否确实体现出了所要求的能力。

在 CAB 办公室进行的评审只能提供一部分所需的证据。这将要求认可机构实施见证评审,以完成对 CAB 认可范围的评审。

认可见证评审是确认 CAB 能力的一个有效工具,为决定是否授予或保持认可范围提供重要的帮助。

在决定授予或保持认可前进行的见证的数量取决于一系列需要由认可机构判断的因素。这些判断需要基于对风险的考虑。

认可机构应当合理地考虑到,CAB 可能为认可见证评审准备最好的审核组，这可能不能反应 CAB 能力的平均水平。因此，我们建议由认可机构来选择要见证的 CAB 审核员（和/或审核地点）。

如果认可机构出于任何理由选择对见证活动做出限制,那么它对 CAB 场所的评审就应当内容更广，例如应当包括与 CAB 审核员进行面谈，以便至少“在理论上”确认其在特定合格评定领域正确工作的能力。另外，对记录（例如审核报告）的检查应当尽可能全面和详尽，因为逐句逐行的审阅可能有助于判断报告撰写人的真实能力。

日期：2007 年 1 月 19 日

认可评审实践工作组指南

IAF GD2附件2“审核时间”的符合性评审

确保管理体系认证的价值和可信性的一个关键问题是配备审核资源。审核资源是指对 QMS 符合适用要求的情况进行有效、可靠的审核所需的有能力的审核员数量和审核时间。QMS 认证机构必须配备足够的审核资源。本文件的指南针对认可机构应当怎样根据 IAF 指南来评审认证机构是否解决好了这个问题。

当认可机构根据 IAF 对 ISO/IEC 导则 62 的应用指南（IAF GD2）对认证机构审核活动的符合性进行评审时，认可评审组应当采取基于过程的评审方法，而不是“检查单”方法。

认可评审的目的应当是确定认证 机构是否按照自己的程序来实施审核，这些程序是否遵循了 IAF GD2 附件 2 的原理，是否考虑了与下列方面相关联的风险:

- 拟审核 QMS 所覆盖的产品和过程;
- 受审核方的行业领域;
- QMS 用到的组织资源和人力资源。

IAF 指南的目的是为认证机构确定自己的审核准则提供一个框架，并就下列方面给出了建议:

- 配置满足能力要求的人力资源（例如审核员）;
- 使用适宜的程序或指导书;
- 根据审核的条件，正确地为实施有效、可靠的审核分配时间。

认证机构的规则可以允许根据审核员的知识、技能和专业能力对这些因素进行调整。

附件 2 不是要规定最短或最长的时间（表示为审核员人天数），而且，认证机构在贯彻 IAF 指南关于实施有效审核的意图时，以及在认可评审组对认证机构的贯彻情况进行评审时，不宜脱离实际情况机械地照搬附件 2。

认可评审组需要确定，认证机构是否建立了一个过程，来确保在任何情况下，都为审核的实施配置足够的时间和资源，以及认证机构是否能够证实该过程是有效的。

请注意，在采用上述过程分配审核时间时，一些情况下，所需的审核时间可能少于附件 2 表中给出的时间，而在另一些情况下，所需的审核时间可能要多于附件 2 表中给出的时间。

从实际操作的角度来说，认可评审可以分为三步走:

1. 对认证机构过程的合理性进行验证（第 1 步);
2. 评价认证机构人员对上述过程的理解和正确应用情况（第 2 步）;
3. 在审查相关记录的基础上,寻找过程得到有效实施的证据(第 3 步)。

第 1 步

该步骤的目的是验证下列方面:

- 认证机构的过程和程序建立在附件 2 所述的分析方法之上;
- 已正确识别了与受审核方的经济活动领域相关联的风险，而且有相应的指导书可以用于正确地处理这些风险;
- 该过程正确地考虑了认证机构从不同行业和不同类型组织（例如大型组织和小型组织，国内组织和跨国组织，服务行业和制造行业，等等）的审核中获得的经验;
- 对偏离附件 2 数量限制的情况，该过程有相应的机制来判断该偏离是否合理正当。

第 2 步

该步骤宜评审:

- 认证机构参与该过程的所有人员对过程本身都有着充分的了解和一致的理解，包括应收集的数据和信息以及应做的记录;
- 上述人员经评定有能力从事所作的工作。

第 3 步

该步骤宜评审相关的记录以确认:

a) 认证机构已按照确定的程序实现了该过程;

(注：如果认可评审组发现任何违反这些程序的情况，都宜开具不符合，不管审核时间是否存在问题)。

b) 可以获得相应的信息来为审核时间的确定提供支持，并为判断偏离附件 2 所述审核时间的情况是否合理正当提供支持。

认可评审组应仔细审查认证机构在确定审核时间时所考虑的因素，特别是偏离附件 2 审核时间的情况所依据的准则。认可评审员尤其宜检查减少审核时间的情况，但这并不排除对增加审核时间的情况进行审查。

认可评审组在判断审核时间是否合理时，宜考虑到审核时间应当足以对 QMS 进行全面检查，识别关键区域可能存在的问题，以及在通常情况下为受审核方提供增值。

如果认可评审组发现上述因素和准则没有形成文件，或者发现它们不清楚、理由不充分或不符合附件 2 的原理和上述基本原则，则应开具不符合。

如果发现一个认证机构的审核时间总是与附件 2 表中的数值保持一致，宜引起认可评审组的警觉。这种情况下，认可评审组宜要求认证机构提供证据，证明这些审核时间确实足以对质量管理体系一致地提供满足顾客和法规要求的产品和服务的能力进行审核。

当然，如果所用的审核时间少于附件 2 表中的数值，除非这种减少有非常好的理由，并且这些理由能够被认证机构的过程清晰地、客观地证实，否则上述要求将不太可能得到满足。

认可评审组在向认证机构管理层提出不符合时，宜清晰说明不符合的原因，该原因应基于对认证机构过程的正确分析，并有已发现的证据提供支持。

认可评审组对认证机构进行见证评审，将有助于确认认证机构符合 IAF 指南的情况。

日期：2007 年 1 月 19 日

认可评审实践工作组指南

对合格评定机构公正性委员会的评审

本文件提供的指南针对认可机构应当怎样根据适用要求，对合格评定机构（CAB）负责确保公正性的组织机构进行评审。这些指南的目的是澄清经常出现的对此问题的疑问，并加强不同认可机构之间评审方式的一致性。

从事管理体系（MS）认证的 CAB 按照标准的要求，需要有一个形成文件的组织结构来确保 CAB 及其运作的公正性，例如一个公正性委员会，或一个具有同等作用的组织机构。

公正性结构需要使所有相关方参与制定与 CAB 认证制度的内容与功能有关的政策和原则。

公正性结构应有权对下列方面进行审查，并要求 CAB 采取相应的行动:

- CAB 当前的活动和拟进行的活动;
- 关键人员的能力，以及
- 与 CAB 运作关联的潜在风险。

CAB 需要在三个层次上确保公正性:

- 战略和政策;
- 认证决定;
- 审核。

公正性结构需要在所有三个层次上确保公正性。公正性结构可以是一个独立的组织机构，也可以与管理职能结合在一起（只要没有任何一个利益方处于主导和支配地位）。为确保没有任何一方处于主导和支配

地位，公正性结构应有正式的规则来确定各成员的权利和义务，例如关于会议出席人数、法定人数和表决的规则。公正性结构中可以有 CAB 管理层的代表，但应有相应的措施确保其不处于支配地位。

公正性结构的一项功能是确保商业利益或其他方面的考虑不会妨碍以客观的方式提供认证服务。在 CAB 所有者的商业利益可以影响关于认证的政策和决定时，这一点尤其重要。

公正性结构及其正式程序规则需要在确立 CAB 法律地位的文件中予以规定，或者以防止对其进行不利于维护公正性的修改的其他方式予以确定。这种方式可以是赋予公正性结构批准政策和一些重要程序（比如公正性结构自身运作的程序规则）的权力。

CAB 应当确保公正性结构代表了利益相关方，且没有一方处于支配地位。这些利益方包括 CAB 自身、政府主管部门、非政府组织（例如环保组织、工会等，取决于认证制度的类型）、咨询机构、专家学者以及 CAB 的经认可的合格评定服务的中间用户（工业界）和最终用户（消费者）。

我们希望公正性结构是一个以确保公正性为职责的高端群体，而不是一个主要以技术/行业领域为基础的群体。

我们尤其不希望根据 CAB 活动覆盖的专业技术领域来确定该群体的组成。但是，公正性结构在工作时，如果需要，可以从技术专家那里获取技术支持。

该群体的成员应当签署保密声明和无利益冲突声明。

CAB 要证实其识别和吸纳利益相关方的过程是充分的，公正性结构自身要证实相关方的参与是充分的。

为了能够提供正确和公正的认证，CAB 管理层应当提供公正性结构履行其职责所需的全部信息，包括（但不限于）下列事项的理由:

- 所有的重要决定和行动，以及
- 选择认证中特定活动的负责人员。

认可评审员应当从下列方面对公正性结构组成的合理性和运作的有效性进行验证:

1. 检查公正性结构的组成、所代表的利益方以及为公正性结构提供的专业支持（需要时）;
2. 验证公正性结构是否遵循了有关的程序规则，检查其履行职责的一般方式;
3. 考虑公正性结构是否有能力及时进行干预，以回应 CAB 变化着的需求;
4. 评价公正性结构的输出的充分性和有效性。
5. 考虑管理层提交给公正性结构的报告的内容和准确性。
6. 确定CAB是否向公正性结构通报了外部评审的结果和认可机构的评审意见。

这可以通过以下方式实现:

- 审查公正性结构的会议议程、会议纪要或其他会议文件;
- 检查会议的参加情况（包括涉及到技术问题时，必要的专业技术人员的出席情况），和（或）;
- 认可机构代表作为观察员参加会议。

日期：2007 年 7 月 25 日

认可评审实践工作组指南

评审认证机构的专业能力和提供可信结果的能力——关键准则

本文件对认可机构在管理体系认证机构认可评审中需要审查的两个关键问题提供了指南，以便认可机构采取有效的、关注结果的认可方法。

这两个关键问题是:

- 认证机构的技术活动管理过程（特别是确保在认可范围内，有能力的审核员在审核中有效运用其能力的过程）;
- 认证机构对审核报告详细程度的要求。

1. 认证机构的能力管理系统

认证机构的“能力管理系统”体现为认证机构为确保有能力的审核员在审核中有效运用其能力而使用的过程和资源组合。

该系统的组成要素包括对资源的总体管理和为特定的审核活动配置资源。

a) 资源管理

认证机构的能力管理系统需要在资源管理方面解决以下问题:

- 认证机构怎样对其技术活动进行评审，以便:
  - 确定其审核员所需的能力;
  - 确定对审核报告进行独立审查的人员;
  - 确定审核员能力的评价人员;
- 能力准则的规定;
- 审核员和技术专家的聘用和培训;
- 根据规定的能力准则，对审核员的经证实的表现进行评价;

- 审核员能力的保持(包括持续监视审核员能力的过程，该过程要考虑来自独立审查审核报告的人员/审核员能力评价人员对审核员能力的意见反馈）；
- 职业发展（能力的改进）。

b) 为特定审核活动配置资源

对于为特定审核活动配置资源，认证机构的能力管理系统需要解决以下问题:

- 怎样审查客户的申请，并确定审核组需要的相关能力;
- 正确地选择和委派审核员和技术专家（如果需要）;
- 正确地选择和委派独立的复核/评价人员。.

上述过程应当覆盖认可范围覆盖的所有活动，或者说认可范围覆盖的不同类型的管理体系 (QMS, EMS, OHSAS, ISMS, FSMS 等等)和每类管理体系中适用的技术活动。认证机构对其能力管理系统要求到何种程度，将取决于上述技术活动涉及的产品和过程的复杂程度和风险。

认证机构应当向认可机构证实，上述过程已经建立，并得到适宜的管理，这种证实应当使认可机构相信认证机构有能力进行严格的审核。

认可机构应当对认证机构的能力管理系统进行全面彻底的评审。对于应用该系统的那些活动，评审人员应当具有关于这些活动的特定专业知识。

认可评审应当:

- 评价认证机构的能力管理系统是否符合所有上述准则;
- 通过审查相关文件，检查认证机构是否符合自己对能力管理系统的要求;
- 与认证机构中负责不同技术活动的管理人员进行面谈，并抽取一些被认证机构委派从事这些技术活动的审核员进行面谈。

2. 审核报告

审核报告对审核结果的描述的详细程度，应当足以使认证机构根据充分的信息做出正确的认证决定。因此，认可机构需要对审核报告的质量进行评价。

审核报告应当:

- 明确说明所审核的管理体系是否有能力以一致的方式满足相关标准的目标;
- 为上述说明提供支持的客观证据的详细内容。

我们认为如果审核报告仅包括标准条款的检查表和少得不能再少的符合性证据，外加一些简短的审核笔记，那么该审核报告是不充分的。

认可机构需要认真评审认证机构对审核报告的要求，以确认其报告的充分性，及其独立复核的充分性。为此认可机构可能需要使用技术专家。

当认可机构质疑一份审核报告的充分性时，或者觉得需要寻求进一步的澄清时，同时有证据表明认证机构对该报告的独立复核也得出了相似的结论，这应当被看作认证机构认证过程有效性的肯定性证据。

日期：2007 年 7 月 25 日

认可评审实践工作组指南

对基于 ISO 9001:2000 的认证机构管理体系进行评审（ISO/IEC 17021 第 10 章，方式 1）

本文件的指南针对认可机构对选择按照 ISO/IEC 17021 第 10 章方式 1 建立的认证机构管理体系的评审，以便帮助改进评审的有效性。

1. 介绍

ISO/IEC 17021 条款 10.1 要求“认证机构除了满足第 5 章至第 9 章的要求外，还应按照下列要求”之一建立管理体系:

a) 与 ISO 9001 一致的管理体系要求（见 10.2），或

b) 通用的管理体现要求（见 10.3)”。

请注意，是认证机构自己来决定选择哪种方式来实施其管理体系。还要注意的是标准没有说推荐哪种方式或优先考虑那种方式。认可机构不应当在接受认证机构的认可申请之前或之后，强迫认证机构采用某种方式。

认证机构选择方式 1 或方式 2 来建立管理体系，将影响到认可机构需要采取的评审方法。认可机构必须准备好对认证机构采取的任何一种方式进行评审。

注：本文件不打算为方式 2 提供指南。

2. 认可机构的评审方式

作为其认可准则的一部分，认可机构应当要求认证机构明确其根据第 10 章采用哪一种方式。

尽管对不同的方式适用的要求不同，认可机构应当使其评审组有能力根据适用于认证机构所用方式的要求进行评审。如果认可机构评审组

对相关标准（采用方式 1 时，包括 ISO 9001）没有足够的知识，那么不太可能具备评审所需的能力。

对于选择方式 1 的认证机构，除了满足 ISO/IEC 17021 第 5 章至第 9 章的要求外，还应满足 10.2 的要求。

认证机构尤其应满足“按照 ISO 9001 的要求，建立和保持一个能够支撑并证实其始终满足本标准要求的管理体系。该管理体系还应满足 10.2.2～10.2.5 的补充要求”。

这就是说，对于采用方式 1 的认证机构，ISO 9001 也是认可准则的一部分，认可机构的评审组要熟悉 ISO 9001 的要求并有能力按照 ISO 9001 进行评审。

如果认证机构宣称自己选择了方式 1，我们不应当期望认可评审完全按照 ISO 9001 进行评审，因为没有这个要求。认可机构对采用方式 1 的认证机构管理体系的评审从来都不是为了由认可机构对 CB 进行 ISO 9001 认证。

另一方面，只按照 ISO/IEC 17021 第 5 章到第 9 章进行评审，并不意味着 ISO/IEC 17021 的所有要求都满足了。在有些部分，还有必要根据 ISO 9001 进行部分评审。

例如，第 5 章到第 9 章没有要求 CB 进行内部审核或采取纠正或预防措施，但不管 CB 采用两种方式中的哪一种建立管理体系，ISO/IEC 17021 第 10 章都要求 CB 进行上述工作。

在方式 1 的情况下，认可机构将需要严格按照 ISO 9001 的要求对 CB 的符合性进行评审。

此外，在评审相对于 ISO 9001 的管理体系要求的符合性时，认可机构必须考虑到 ISO 9001 的某些要求在方式 1 中被强化了。

采用方式 1 的认证机构需要充分了解如何采用“过程方法”来建立和实施管理体系，因为这是 ISO 9001 的基础要求。认可评审员还需要熟

悉“过程方法”，以便有能力对方式 1 进行评审，并应当在评审方法中考虑过程方法。

日期：2004 年 10 月 14 日

ISO 9001 审核实践组指南

对两阶段审核方式的需求

ISO 9001:2000 审核需要审核员对受审核方的质量管理体系（QMS）和业务性质有好的理解。因此，在认证审核之前访问受审核组织并进行第一阶段审核是有益的。

第一阶段审核主要是为了确定认证审核（第二阶段审核）的范围和策划认证审核，并使审核员了解受审核组织。例如，了解组织的 QMS、方针和政策、目标、风险、过程、场所等等。认证机构还可以通过第一阶段审核，将自己的需求和期望传达给受审核方。

作为认证审核的准备阶段，第一阶段审核实施的活动包括:

- 确定组织业务的关键风险以及相关的法律法规和遵守情况;
- 评价受审核方所确定的过程能否充分满足其目标和顾客要求;
- 文件审查;
- 文件审查应当确定组织的 QMS 文件是否充分覆盖了 ISO 9001:2000 的所有要求。评审通常在受审核方现场进行（除非有其他请求并有合理理由）。文件审查应当提交一份指出所有不足之处的报告。在文件审查中，审核员应当评价支持性程序和过程说明的程度与可用性，并收集关于组织管理体系范围、过程和场所的必要信息;
- 起草拟颁发的认证文件，包括对认证范围的说明;
- 策划认证审核（第二阶段），包括对挑选审核组的要求;
- 获取内部审核和管理评审得到有效策划或实施的证据;
- 检查 QMS 是否得到实施并可以接受第二阶段审核，包括检查适当层次的文件和支持性记录;

如果体系存在任何不足，审核员应当在审核报告中指出，以便组织有机会在认证审核（第二阶段）前进行调整。

- 商定第二阶段审核的日期。

日期：2004 年 11 月 10 日

ISO 9001审核实践组指南

过程的识别

1. 区分过程和活动的概念

如果受审核方不能区分过程和活动的概念，审核员可以使用ISO 9000:2000中的指南（条款2.4）和定义（条款3.4.1）作为背景信息来简要解释两者的不同。审核员必须能够适应受审核方所处的情况。理解受审核方的体系和方法是审核员的职责。

在审核中，审核员应当确定所面对的问题是否只是受审核方使用不同的术语，还是受审核方并没有真正地实施过程方法。如果受审核方没有完全贯彻ISO 9001:2000条款4.1的要求，审核员可能需要开出不符合报告。如果受审核方满足了条款4.1的所有要求，只是使用不同的术语，那么审核员应当不必开出不符合报告。

受审核方只要满足了标准的要求，就有权使用自己的术语。审核员应当在头脑里将受审核方所用术语与标准术语进行对照，以确保一致性和更好地理解。

2. 过程应有确定的目标、输入、输出、活动和资源

如果受审核方不理解一个过程必须有确定的（但不一定是可测量的）目标、输入、输出、活动和资源，审核员应当试着换一种方式向受审核方提问，而避免使用质量管理的专业术语，例如：你可以说明一下你们在这里的运作吗？你的部门的基本工作是什么？你在开始工作时需要哪些信息？这些信息来自何处？谁接收你的工作结果？你怎么能知道你的工作是否做得对？等等。

这应当有助于审核员确定受审核方是否已明确了过程（按ISO 9001:2000），过程是否有清晰的输入、输出、目标等。

3. 过程应当得到分析、监视/测量和改进

如果审核员在使用上述审核方法后，发现缺乏记录或证据来证实过程得到了分析、监视、测量和改进，这将不符合ISO 9001:2000条款4.1。

4. 受审核方/审核员认为ISO 9001:2000的每一章或子条款都必须是一个单独的过程

如果审核员有这种认识，他应当去阅读相关的ISO文件（特别是ISO/TC176对ISO 9000的介绍和支持文件包中的N544《对过程方法的概念和使用的指南》），而后就会明白这种认识是错误的。

如果受审核方有这种认识，推荐审核员使用上面第2部分所述的方法。

5. ISO 9001:2000“引言”中阐述的过程方法是否是标准的要求?

ISO 9001:2000“引言”对过程方法的阐述完全是资料性的，其本身不是增加的要求。条款4.1规定了对质量管理体系过程采用过程方法所需的步骤。条款4.1的注提供了质量管理体系所需过程的实例。审核方法必须以此为基础，对组织的过程进行分析。

理解过程方法

帮助审核员理解过程方法

如果审核员不理解或没有正确理解过程方法，可以指导他去参阅公认的介绍材料，如国际标准ISO 9000:2000《质量管理体系－基础和术语》以及ISO/TC176编写的《管理体系过程方法的概念与应用》（文件编号：ISO/TC176/SC2/N544，可从http://www.iso.org/tc176/sc2下载）。

认证机构宜确保所有审核员都接受了关于ISO 9001:2000新要求的充分培训，特别是关于过程方法的培训。这样，审核员宜认识到过程方法包含以下方面：

- 确定实现组织质量目标所需的过程和职责；
- 确定并提供所需的资源和信息；
- 建立并应用对每个过程进行监视和（或）测量及分析的方法；
- 建立并应用持续改进质量管理体系有效性的过程。

审核员必须充分理解过程方法的概念，以便不拘泥于标准中的术语；受审核方也可以使用他们自己的术语。审核员必须意识到过程方法在各个组织中的应用是不同的，取决于组织及其活动的规模和复杂程度。审核员宜特别注意中小企业的情况，不宜期望在这类企业的质量管理体系中会有很多过程。

帮助受审核方理解过程方法

如果受审核方完全没有正确理解过程方法，那么审核员通常宜在第一阶段审核中发现这一问题。

审核员宜向受审核方谈起公认的介绍材料（如上一节所述的材料，

特别是ISO/TC176/SC2/N544介绍了过程方法的各个步骤并提供了有用的指南和示例）。

受审核方也宜充分考虑:

- 过程目标的建立,
- 过程的策划,
- 是否有适宜的记录。

受审核方常常识别出过多的“过程”，其中一些（甚至是全部）只是一项活动，并不符合ISO 9000:2000对“过程”的定义。在这种情况下，审核员宜（在第一阶段审核时）建议受审核方重新界定其过程（例如根据活动的关键程度），这一点可能对中小企业尤为重要。

日期：2004 年 10 月 14 日

ISO 9001 审核实践组指南

确定“适当时”的过程

术语

当受审核方使用的术语与审核员所用的不同时，审核员应当根据 ISO 9000:2000 中的术语来理解 ISO 9001:2000 中的概念，并在头脑里或纸面上将受审核方和审核员自己对同一概念使用的术语进行对照，而避免使用质量管理的专业术语。

过程的确定

如果受审核方和审核员对过程的确定有不同的理解，那么审核员应当设法理解受审核方的观点，而不要把自己的观点强加于人，除非受审核方明显不满足标准的要求（需要有充分的客观证据来证明）。如果审核员认为受审核方没有正确地识别或漏掉了某些过程，也适用上述的处理方法。

删减

审核员应当参照 ISO 9001:2000 条款 1.2、ISO/TC176 对 ISO9001:2000 条款 1.2 款“应用”的指南（ISO 9000 介绍和支持文件包中的 ISO/TC176/SC2/N524）以及 APG 对质量管理体系范围的指南。

审核员应当在得到受审核方不能删减某项要求的客观证据后再做出结论。

在解决与受审核方的争论时，一个好的做法是审核员借助 ISO9000:2000《质量管理体系：基础和术语》以及 ISO/TC176/SC2/N524 来向受审核方解释自己的观点。

日期：2004 年 10 月 14 日

ISO 9001 审核实践组指南

审核含有“适当时”的要求

受审核组织应当确定如何实施ISO 9001中含有“适当时”的要求,因为这将影响到组织满足顾客要求能力。（请受审核方关注ISO 9001:2000条款1.1“本标准为有下列需求的组织规定了质量管理体系要求：a)需要证实其有能力稳定地提供满足顾客和适用的法律法规要求的产品……”，可能是有用的)

审核员应当确定含有“适当时”的要求对于受审核方申请的/实际的质量管理体系范围来说是否确实是相关的、适用的。因此，在审核中应当以此为基准来决定什么是适当的、适用的，或者什么是不适用的。

审核应当考虑的问题包括:

- 如果不实施相关要求中带有“适当时”的那一部分，会不会影响对组织质量管理体系的信心,或者上述要求对建立信心是否仍有价值?
- 如果不实施相关要求中带有“适当时”的那一部分，是否增加了组织不满足顾客要求的风险?（这里不仅包括一组特定的顾客要求，还包括最终用户、消费者或供应链的需求和期望）

需要有经验对技术问题作出判断

审核机构应当能够证明其审核员具有必要的行业知识、能力和审核技能。审核员需要能够证明自己对于所检查的过程有相关的知识，并需要应用他们的技能来评价含有“适当时”的要求是否是相关的、适用的。

审核员需要理解含有“适当时”的要求是怎样与过程的建立方式和所期望的输出结合起来的。如果认为某项要求不相关、不适用，那么审核应当提供客观证据来证明体系是有效的、顾客要求持续地得到了满足。

审核机构应当有必要的过程来确保审核员对于所审核的组织具有相关的特定技能。

日期：2004 年 10 月 14 日

ISO 9001 审核实践组指南

证明对标准的符合性

（“按照标准条款进行审核”与“按照受审核方的过程进行审核”）

在评价对标准的符合性时，审核检查表可能是不充分的

在审核结束时，审核员应当能够知道标准的所有要求是否得到了满足。

为了试图证明对标准的符合性，人们常常求助于检查单，这样审核员能够对标准的要求逐一进行检查，确保审核覆盖了所有要求。这种填写检查表的基本方法是一种确保审核检查了标准的所有要求的简单作法。但是，考虑到 ISO 9001:2000 所提供的方法，按照通用的检查表进行审核可能妨碍审核员收集过程之间有效衔接的证据。

在有些情况下，完全摆脱检查表（或审核问题清单）也许是不可能的，特别是当组织需向第三方（例如监管机构、合格评定机构）提供符合标准的证据时。

因此，重要的是以适当的方式在适当的时间使用检查表，也就是把检查表作为帮助审核员明了需要审核的标准要求的工具。

什么是充分的抽样?

没有统计公式或数学公式来确定审核中抽样的正确数量。规定一个为确认符合性而需要抽取的样本数量（例如，针对一个特定要求抽取 1 个、5 个甚至更多个记录）不是有效的做法，而且并不能确保符合性。当然，增加抽样数量会使审核员对 QMS 实施的真实情况更有信心，这是一个事实。因此，从这个意义上讲，“充分的”抽样，是指审核员在现场进行面谈和检查记录时抽样的程度足以使审核员相信受审核方所描述的

QMS 实施情况。

IAF 对 ISO/IEC 导则 62 的应用指南附件 2 阐述了多场所抽样或对一个组织内部的多个部门的抽样，并规定了相应的现场审核时间和多场所抽样公式。

审核员需要进行面谈，并在面谈中检查记录和证据。需要抽取的样本数量取决于被审核过程的复杂程度，以及面谈中从受审核方得到的信息的质量。审核员遵守审核计划中规定的时间进度也同样重要。在审核即将结束时，审核员需要确保所看到的样本及客观证据具有代表性，以便对 QMS 的实施情况做出适当的结论。

记录审核信息

ISO 19011 和 IAF 对应用 ISO/IEC 导则 62 的应用指南解释了审核报告应当包含的内容。但是，重要的是给受审核方的审核报告只包含对他来说重要的信息，例如，潜在的改进机会、正面的观察意见以及对标准的不符合，受审核方并不希望审核报告只是重复和解释标准的要求。

审核员可能需要证明实施审核的顺序，有时也叫做审核路径。对审核员来说，做审核笔记是记录审核过程的非常有效的方法。但是审核笔记的主要缺点是审核信息的记录方式取决于审核员个人，不同审核员之间记录的详细程度和风格会有很大不同。

检查表可以在一定程度上确保审核员之间的一致性。但是审核员绝不应当忘记他们的时间是用来审核的，而不是用来填写检查表或者做笔记的。

将对具体任务、活动或过程的审核与整个体系相联系

审核员不应当偏于关注过多的细节，而失去了对审核整体方向的把握。重要的是审核员要关注受审核方质量手册或文件中对过程之间的相互作用做出规定的那些信息。审核员与受审核方进行面谈的方式，应当使审核员能够确定被审核过程的输入和输出。在头脑中记住受审核方的过程图，可以确保审核员在任何时候都能确定其正在审核的过程的重要性，从而能够始终把握住审核的整体方向，这也会帮助审核员理解过程之间的联系。

审核时，审核员会有机会去检查受审核方对于其过程相互关系的描述。审核员应当抽取一些样本以了解该描述是否恰当地反映了过程之间实际的相互关系，这将有助于确定过程描述的充分性与适宜性。

日期：2004 年 10 月 14 日

ISO 9001 审核实践组指南

对持续改进的审核

改进多少才“足够”？

应该强调 ISO 9001:2000 的要求是为了持续改进质量管理体系的有效性。

持续改进的动力是最高管理层设立的目标，持续改进至少应当涉及：内部效率（为保持组织的经济竞争力）的改进，每个顾客的需求以及市场通常的期望的业绩水平。

例如，在航空工业，“可接受”的交付产品的不合格率是零，如果组织根据这个可接受率来设定“改进”的目标，将没有什么用处。然而，如果组织以改进内部效率和竞争力（例如通过创新）为目标，将是有用的。

审核员应该寻求确定受审核方是否试图设定将下面三个因素关联起来的目标：组织的目标、顾客需求和市场期望。而后，组织要平衡对内部效率改进的需求和对外部业绩发展的需要（虽然二者经常密切相关）。孤立的去评价一个方面，是不能发现这个方面是“足够的”还是“欠缺的”。

可能给审核员带来问题的是了解什么是合理的市场基准。再以上述航空工业为例，如果组织宣称，交付产品的不合格率已经从50%降到40%，这也算持续改进，但这种改进是难以接受的，因为该行业可接受的不合格可接受率为零。然而，如果组织宣称将不合格品率从0.50%降到0.40%作为其改进目标，这就大大接近了市场标准。

审核员对待持续改进问题的惟一办法，就是验证组织是如何确定改进率的，如何评价相关风险的，以及如何将改进目标与顾客要求和对顾客满意反馈信息的监控关联起来的。

几乎不可能开出这样陈述的不符合报告：没有足够的持续改进。

哪种信息是有关的？我们能在哪里找到？

审核员必须验证组织的总目标如何被转化为对适宜过程的内部要求，这些要求是如何得到沟通的，以及如何监视这些要求。因此，审核员应当寻找组织对过程监视得到的数据进行分析，进而用分析结果来评价过程效率和(或)改进过程输出的证据。为了确保单个过程的改进不会与实现其它目标发生冲突，审核员特别应当检查对单个过程进行改进的方式，是否在促进实现总体目标方面是一致的。

审核员需寻找的信息是组织的目标如何被转化为具体的QMS目标的证据。例如：一个组织可以设定将顾客投诉降低30%的目标，之前的最高管理层分析表明50%的顾客投诉与延误的交付有关。那么，审核员应当寻找组织正在着眼于各个过程和过程接口对调度和计划活动的关键方面进行监视和分析，以减少延误。

过程改进还是QMS的改进？

审核员应记住：期望一个组织在所有可能改进的方面同时取得进展是不现实的。每项改进都需要有资源的投入，这可能需要最高管理层安排优先顺序，特别是在需要投资时。审核员应该寻求确保改进目标在总体上是一致的，并与上面提到的三个因素有着内在联系。然而，如果一个组织没有与持续改进有关的方针和目标，很明显是不符合标准要求的。相似的，如果没有组织在这些方面中至少一个方面进行改进的证据，也应当被认为表明组织的质量方针与ISO 9001:2000不符。

注意：不要求组织对所有过程同时设定改进的目标。正如上述降低顾客投诉的例子，如果最高管理层认为有些过程对减少延误的作用不大，那么组织不特别关注这些方面是正常的。

如果最高管理层对某一过程设定了现实可行的目标，但没有改进的证据，那么这一信息必须被反馈给管理评审，以便最高管理层能够决定什么样的措施是适当的。例如，重新调整目标或采取其他措施来影响该过程。

对仅有最低数量的文件的 QMS 进行审核

当受审核方只出示质量手册和 ISO 9001:2000 专门要求的 6 个程序文件时，审核员与受审核方之间可能会在是否缺少某些文件化程序的问题上有不同意见。

审核员与受审核方在这点上的意见分歧，是由于对 ISO 9001:2000 条款 4.2.1 的要求及相关的“注”的理解不同而造成的。

“4.2.1 总则

质量管理体系文件应包括:

……

d)组织为确保其过程的有效策划，运行和控制所需的文件。

注 2: 不同组织的质量管理体系文件的多少和详略程度取决于:

a 组织的规模和活动的类型;

b 过程及其相互作用的复杂程度;

c 人员的能力。”

审核员应请受审核方介绍运作过程，然后提出问题，记录回答情况，并观察各级工作人员（包括管理人员，过程所有者和操作人员），以确认实际工作状态符合所给出的描述。

然后，应当根据所观察到的在保持一致性方面的需要，以及文件在避免重大的、已识别的风险方面的作用来评价文件的必要性。

请读者参考 ISO 9000 介绍和支持系列文件的 ISO/TC176/SC2/N525《关于 ISO9001:2000 对文件的要求的指南》给出的建议。

日期：2004年10月14日

ISO 9001 审核实践组指南

怎样审核最高管理层过程

审核最高管理层是一个敏感的问题，本文件为这类审核提供了指南。

审核员应当使最高管理层参与到审核当中，即：邀请他们参加首、末次会议，在审核计划中安排足够的时间与最高管理人员交谈，直接与他们讨论审核发现，寻找他们的承诺的证据等等。重要的是审核员要把关注点从质量经理转移到注意组织的最高管理层身上。

审核员应当把最高管理层的活动看作过程，并相应地对之进行审核。

策划阶段：

审核员需要识别最高管理过程，并：

a) 通过审查像组织结构图、年度报告、经营计划，公司简介、新闻报道、网站这样的资料来了解组织及其管理结构；
b) 在审核计划中安排通过与最高管理层面谈直接收集最高管理层承诺的相关信息；
c) 了解组织及其最高管理层的文化，以确定其对审核计划的影响，并做出适当的调整；
d) 通过确定组织的着装规定，要求审核员的着装和仪表体现职业化；
e) 策划与最高管理层面谈的时间安排，以确保便利和准时。

不应当安排审核经验有限的审核员去与最高管理层面谈。

实施审核：

评价最高管理者承诺的常用方法是:

1、 与最高管理层面谈

审核员可以通过使用对最高管理层适宜的经营术语来提出相关问题，以便:

a）获取最高管理层对质量的认识和承诺及其与组织总体目标和管理体系的相关程度等方面的证据;

b）证明是否符合 ISO 9001 关于管理职责的要求。

2、 收集和确认证据

审核员/审核组应当不断寻找机会来确认最高管理层在面谈中所作的回答。

这包括:

a) 评价方针和目标的实用性和相关性;

b) 建立方针和目标之间的联系;

c) 获取方针和目标有效并在整个组织内得到理解的证据;

d) 确定方针和目标对 QMS 的持续改进和实现顾客满意是否适宜;

e) 确定最高管理层是否参与了管理评审。

为了提供必须的证实，审核员可能需要进一步与最高管理层面谈并收集证据。

审核组应当确保对任何证明最高管理层承诺的补充证据进行了收集。

审核员/审核组应当评价所收集到的证据，以确保信息的完整性和准确性，并使所做的结论具有可信性。

审核报告

审核员在编制审核报告时，应当使报告适宜于提交给组织的最高管理层。向最高管理层和组织的关键利益相关方提交一份适宜的审核报告

摘要可能是适当的做法。摘要应当突出关键的审核发现（正面的和负面的）并识别改进机会。

日期：2004 年 10 月 14 日

ISO 9001 审核实践组指南

审核检查表的作用和价值

引言

本文件介绍了检查表的作用和使用，以求积极为审核过程提供支持。

本文件主要为外部审核机构（包括认证机构）提供指导，且任何实施内部审核的组织同样可以参考本文件。

对检查表的需求

注意现行的审核标准 ISO 19011 在 6.4.3 款中写道：“编写工作文件”。条款中有以下内容:

“审核组成员应当评审与其所承担的审核工作有关的信息，并准备必要的工作文件，用于审核过程中的参考和记录，这些工作文件可以包括:

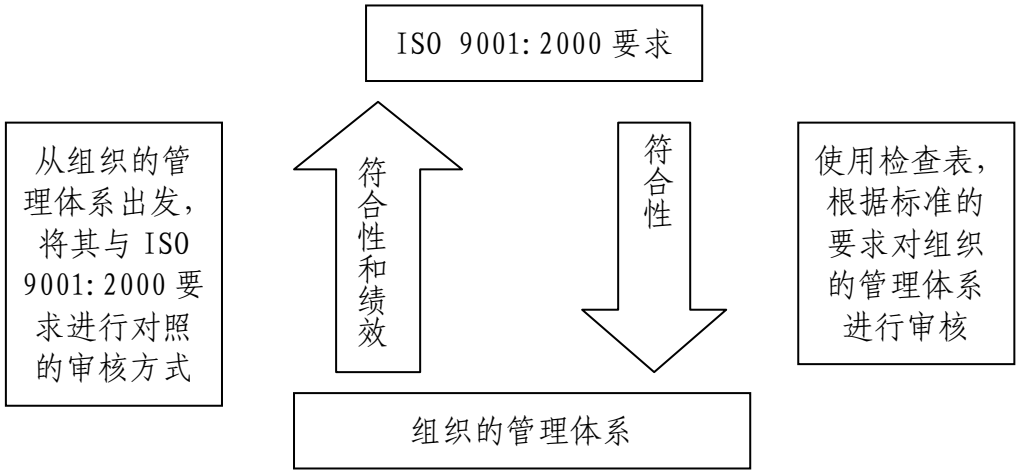
- 检查表和审核抽样计划;
- 记录信息(例如：支持性证据，审核发现和会议记录)的表格。

检查表和表格的使用不应当限制审核活动的内容，审核活动的内容可随着审核中收集信息的结果而发生变化。”

审核检查表的使用

管理体系标准并不总是要求有审核检查表，审核检查表只是帮助审核员进行审核的一种工具。许多组织用检查表来确保审核至少覆盖了审核范围所确定的要求。

下面给出了审核方式的示例:



从组织的质量管理体系出发，将其与标准的要求进行对照的审核方式是有益的。

而检查表可用于确保审核覆盖了所有相关的 ISO 9001 要求。

优点：

市场上可获得的文献资料中对使用审核检查表有如下评论：

(1) 假如是为某一特定的审核而编制的检查表，且使用正确，可以：

a. 有助于审核的策划；

b. 确保一致的审核方式；

c. 用作抽样计划和控制时间的工具；

d. 帮助记忆；

e. 保存审核过程中收集的笔记（现场审核笔记）。

(2) 审核检查表的编制方式需要有助于审核过程；

(3) 需要培训审核员如何使用特定的检查表，告诉他们如何通过良好的提问方法，使用检查表获取最多的信息；

(4) 审核过程中，检查表应当帮助审核员更好地工作；

(5) 检查表有助于确保以系统的、全面的方式进行审核，确保获得充分的证据；

(6) 检查表可以为一次审核提供结构性和连续性，可以确保遵循审核范围;

(7) 检查表可以提供一个沟通的工具和记录数据的地方，以备日后引用;

(8) 完整的检查表提供审核已实施的客观证据;

(9) 检查表可以记录对 QMS 进行检查的情况;

(10) 检查表可以作为策划以后的审核的信息库;

(11) 可以在现场审核前向受审核方提供检查表。

缺点:

相反，当没有审核检查表可用，或检查表编制得不好时，会存在以下问题:

1、 检查表可能被受审核方看成一种威胁;

2、 检查表的关注范围可能过窄，以至于不能识别出存在问题的特定区域;

3、 检查表是一种辅助审核员工作的工具，但如把它作为审核员的唯一支持工具的话，就会起限制性作用;

4、 检查表不应成为审核策划的替代品;

5、 对于没有经验的审核员来说，如果过分依赖检查表指导提问的话，可能不能清楚的表达他/她正在寻找什么?

6、 编制得很差的检查表，会因为内容的重复或反复而减缓审核速度;

7、 不反映特定组织的管理体系情况的通用检查表，可能不会提供增值，并且会干扰审核;

8、 关注面很窄的检查表会使审核员在评价中提出独特的问题和（或）采用独特的方法的机会最小化。

结论:

用审核检查表有优点也有缺点，这取决于许多因素，包括顾客需求，时间和费用限制，审核员的经验，以及行业性认证制度的要求。审核员应把检查表的价值看作是审核过程中的辅助工具，并考虑将其作为一种功能性的工具。

ISO 9001:2000 的范围、质量管理体系（QMS）的范围和认证的范围

ISO 9001:2000 第 1 章“范围”描述了该**标准本身的范围**。

ISO 9001:2000 标准的范围不宜与 **QMS 的范围**相混淆。QMS 的范围作为一个术语，通常用于描述组织正式实施的 QMS 所覆盖的过程、产品（和/或服务）以及相关的场所、部门等。（注：这不一定包括组织所有的过程、产品、场所或部门）

QMS 的范围应当根据组织的产品及其实现过程的性质、风险评价结果、商业考虑以及合同和法律法规的要求来确定。

ISO 9001：2000 是通用的，适用于所有组织（无论其类型、规模或产品类别如何），在某些条件下，组织可以删减 ISO 9001：2000 第 7 章的一些特定要求，同时声称符合标准。这是因为我们承认并非第 7 章的所有要求与所有组织都相关。ISO 9001：2000 本身在条款 1.2“应用”中允许此类删减。

因此，**认证的范围**包含 **QMS 的范围**，并说明了所删减的 ISO 9001 的任何要求。

由于 **QMS 的范围**和**认证范围**这两个术语经常被互换地使用，所以可能在顾客或最终用户试图识别组织的哪些部分获得了 ISO 9001 认证，哪些生产线或过程被 QMS 所覆盖，或者 ISO 9001 的哪些要求被删减时，经常引起混淆。

为了消除这种混淆，并使人们能够识别到底哪些获得了认证，认证范围应明确说明:

- QMS 的范围（包括其覆盖的生产线和相关场所、部门等的详细情况）；
- 针对 QMS 覆盖的生产线，组织的产品实现或服务交付活动的主要过程（例如设计、生产和交付）；
- 任何被删减的 ISO 9001 要求。

（应当注意，认证范围不同于组织在成功证实自己符合 ISO 9001 后所获**证书**中描述的范围。证书通常对认证范围做一综合说明，但没有对被删减的 ISO 9001 要求的详细描述；但是，证书可以包括一个注解，指出组织的质量手册对删减做了详细描述）

组织在申请认证之前草拟一个认证范围，这一点很有必要。认证机构应当随后在第一阶段审核中对组织草拟的范围进行分析，以便正确地策划第二阶段审核（参见《对两阶段审核方式的需求》）。

审核员的职责是:

- 确保对认证范围的最终说明不产生误导;
- 验证由组织草拟的范围仅包括在认证审核中评价过的过程、产品、场所或部门等;
- 验证由组织草拟范围说明了所有被删减的 ISO 9001 要求，并验证是否提供了删减的合理理由。

此外，为了避免可能使顾客和最终用户产生混淆，组织的质量手册和所有可公开获得的文件（例如促销和营销资料）应当清晰地说明认证范围。

但是，认证范围本身不能包含带有促销性质的陈述。

ISO/TC 176/SC2 为向标准使用者说明 ISO 9001:2000 条款 1.2“应用”的用意，编写了 ISO 9001 介绍和支持系列文件中的 N524《对 ISO 9001:2000 条款 1.2“应用”的指南》。该文件还包括条款 1.2 的实际应

用的典型示例。（N524 可以从 www.iso.org./tc176/sc2 免费下载）。另一个应当遵循的文件是 IAF 发布的《IAF 对 ISO 9001:2000 的应用指南(第二版)》。

日期：2004 年 10 月 14 日

ISO 9001 审核实践组指南

怎样在审核过程中提供增值

增值审核的含义

对于在质量管理体系（QMS）审核过程中“增加价值”的重要性，我们听得很多，但这究竟是什么含义呢？是否有可能不影响审核可信性和完整性或不提供咨询而增值呢？原则上讲，所有审核都应当增值，但实际上并不总是这样。

本文件针对审核怎样才能为审核涉及的各方增值，以及第二方或第三方审核中可能遇到的不同情况提供了指南。

“增值的”QMS

词典中对“价值”有几种定义，但所有定义都着眼于一个概念：***有用***的某物，因此***“提供增值”***意味着使某物***更有用***。

一些组织已经使用ISO 9000系列标准建立了融入其经营方式的QMS，这些QMS对帮助组织实现经营战略目标是***有用的***——换句话说，QMS为组织***增加了价值***。相反，有些组织可能只是简单编写了一套官僚程序和记录，它们并不反映组织实际工作的真实情况，没有什么用处，只增加成本。换句话说，它们没有“增加价值”。

能不能增加价值是一个方法问题:

不增值的方法提出这样的问题: “为了拿到ISO 9000认证，我们得写哪些程序？”

而“增值”方法会这样问: “我们怎样利用ISO 9001:2000质量管理体系来帮助我们改进经营？”

怎样在审核过程中增值

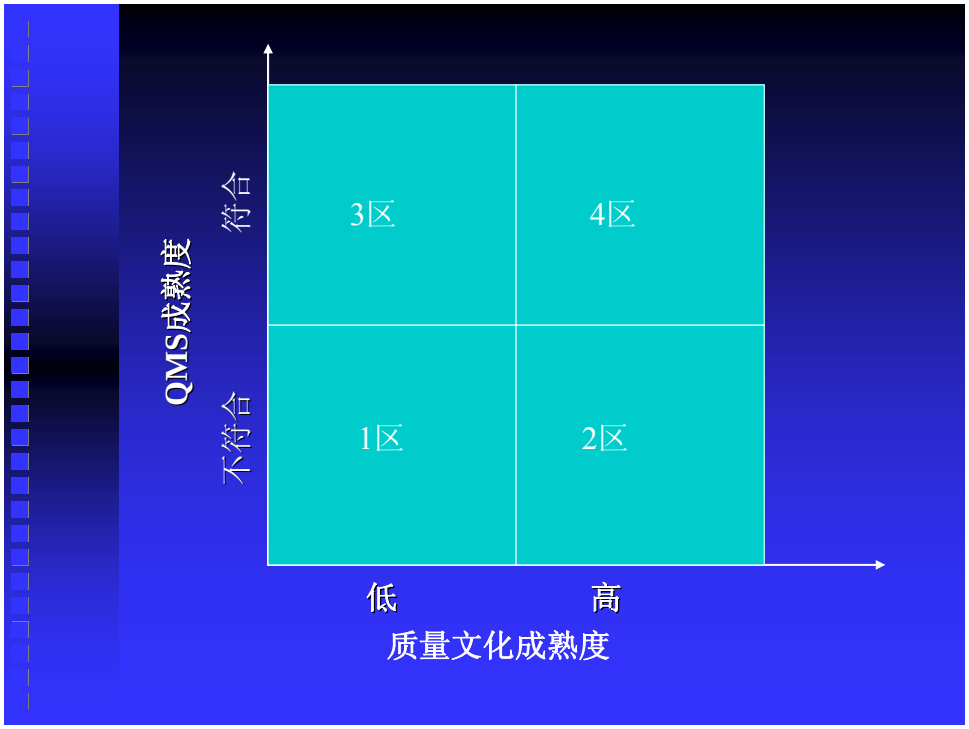
我们怎样才能确保审核对组织保持和改进QMS是***有用的***（但是，我们应当承认除了“增值”，审核也许还需要考虑其他一些方面）？

为了“增值”，第三方审核应当通过以下方式为各方提供帮助：

- 对获证组织：
  - 使最高管理层了解组织实现战略目标的能力；
  - 发现和解决影响组织绩效的问题，从而提高组织的绩效；
  - 发现改进机会和可能存在风险的领域。
- 对组织的顾客：增强组织提供合格产品的能力。
- 对认证机构：提高第三方认证过程的可信性。

“增值”方法很像是一个组织的质量文化成熟度和QMS成熟度（相对于ISO 9001:2000要求）的函数。

通过图1，我们可以从概念上把组织归入以下四个区域：



1区：“质量文化”成熟度低；QMS不成熟，不符合ISO 9001:2000

2区：“质量文化”成熟；QMS不成熟，不符合ISO 9001:2000

3区：“质量文化”成熟度低；QMS成熟，符合ISO 9001：2000

4区：“质量文化”成熟；QMS成熟，符合ISO9001:2000

注：

“质量文化”是指组织在质量方面的意识、承诺、整体态度和行为的程度。

“符合ISO 9001:2000”与组织QMS的成熟度和符合ISO 9001:2000要求的程度有关（我们承认，即使组织的QMS整体成熟度和符合ISO 9001:2000的程度较高，也可能在其中发现特定的轻微不符合）。

1区：（“质量文化”成熟度低，QMS不成熟，不符合ISO 9001:2000)

对于一个几乎或根本没有质量文化而且QMS不符合ISO 9001:2000的组织来说，它可能期望审核通过提供***如何***实施QMS和（或）解决不符合的建议来增加价值。

对于这种审核员必须格外小心，因为在第三方审核中提供这种建议无疑会引起利益冲突，并违反ISO/IEC导则62对认证机构的认可要求。但是，审核员***可以***做的是确保在遇到不符合时，受审核方清楚地理解标准要求的是***什么，为什么***会开具不符合。假如组织能够认识到解决这些不符合将促进绩效的改进，那它就很可能更加信任认证过程，并为之做出更多的努力。但是，审核员**要**报告所有发现的不符合，以使组织清楚地理解为了满足ISO 9001:2000要求需要做***什么***。

尽管在审核结论导致组织不能获得认证时，组织可能不完全满意，但组织的顾客（他们接收组织的产品）从他们的角度肯定会认为这次审核是“有价值的”。从认证机构的角度来说，未能报告所有发现的不符合，和（或）指导组织***如何***实施质量管理体系，都不会为审核这种职业或认证过程的可信性增加价值。

我们必须认识到，上述讨论主要是围绕第三方认证审核的。对于第二方审核（供方评价），没有理由不通过指导组织如何实施QMS来“增加价值”。在这种情况下，这种指导（如果做得好的话）无疑对组织及其

顾客都有帮助。

2区：（“质量文化”成熟；QMS不成熟，不符合ISO 9001:2000）

对于一个“质量文化”成熟，但QMS不成熟、不符合ISO 9001:2000要求的组织来说，它对审核提供增值的基本期望很可能与1区的组织相似，但可能对审核员有更高的期望。

为了能够增值，审核员必须理解组织用于实现ISO 9001:2000要求的现行做法，换句话说，在ISO 9001:2000的框架内去理解组织现在的过程，而不是，例如，坚持让组织重新确定过程、编写文件，以使其与标准条款的结构相一致。

例如，组织的质量管理体系可能建立在卓越绩效模式或全面质量管理工具的基础上，例如Hoshin Kanri（“方针管理”的日文发音）、质量功能展开、FMEA、6σ方法、5S计划、系统地解决问题、质量小组等等。为了能够在增值，审核员至少应当了解组织所采用的方法，以及这些方法对于该组织的有效程度和使组织满足ISO 9001:2000要求的程度。

审核员不“害怕”组织表面上的高复杂程度，这也很重要。当组织把上述这些工具作为整体全面质量理念的一部分时，在使用这些工具的方式方面可能仍有不足。因此，审核员必须能够识别系统性问题并正确地开具不符合项。在这些情况下，组织可能指责审核员过于学究气甚至官僚主义，因此审核员要能够证明所开的不符合项是适当的，这一点很重要。

3区：（“质量文化”成熟度低；QMS成熟，符合ISO9001:2000）

一个获得ISO 9001认证很长一段时间的组织可能能够证明它的QMS符合ISO 9001:2000的程度较高，但却并没有在整个组织内真正建立“质量文化”。典型的情况可能是，组织迫于顾客压力而实施了QMS，这个QMS是比着标准的要求而不是按照组织自己的需求和期望建立的。其结果是

QMS可能与组织日常运作的方式两张皮，造成不必要的负担和低效率。

为了在这些情况下增加价值，审核员的主要目标应当是发挥“催化剂”作用，使组织改进ISO 9001质量管理体系，并将体系与日常运作整合起来。虽然第三方认证审核员不可以在如何满足ISO 9001:2000要求方面提供建议，但却可以***鼓励***和***激发***(但不是***要求！***)组织***超越***标准的要求，而且这确实是一种好的做法。审核员提出的问题（以及提问的方式）可以使组织在怎样使QMS更有效率、更***有用***方面得到宝贵的启发。审核员识别的改进机会应当包括有可能加强QMS有效性的方式，但也可以关注改进***效率***的机会。

4区：（“质量文化”成熟； QMS成熟，符合ISO9001:2000)

对于一个“质量文化”成熟并已通过ISO 9001认证很长时间的组织，它对增值的期望对审核员最具挑战性。这类组织常常抱怨审核员的定期监督审核可能是多余的，在组织看来没有增加什么价值。

在这种情况下，最高管理层成为认证过程的重要顾客。因此，对审核员来说，重要的是清楚地理解组织的战略目标，并能够将QMS审核与此相结合。审核员需要花时间与最高管理层进行详谈，以确定他们对QMS的期望，并把这些期望融入审核准则。

对增值审核的一些提示

1、审核策划

a、理解受审核方的期望/公司文化;

b、有没有需要关注的具体问题（参考以前审核的输出）?

c、分析组织所属行业的风险;

d、预先评价法律/法规要求;

e、为实现审核目标而正确选择审核组;

f、安排足够的审核时间。

2、审核方法

a、多关注过程而不是程序。***有些***程序文件、作业指导书、检查单等对组织策划和控制过程可能是必要的,但是内在动力应当是过程绩效;

b、多关注结果而不是记录。***有些***记录对组织提供过程有效(能够实现所策划的结果)的客观证据可能是必要的。但是为了增加价值,审核员应当了解和肯定其他的证据形式;

c、记住八项质量管理原则;

d、采用PDCA方法评价组织过程的有效性:

I. 过程是否经过了策划?

II. 过程是否按计划进行?

III. 是否实现了所策划的结果?

IV. 是否通过下列方式识别并实现了改进机会?

- 纠正不符合;
- 识别问题的根本原因并采取纠正措施;
- 识别趋势和对预防措施的需求;
- 创新。

e、在审核中采用整体的方式来收集证据,而不是着眼于ISO 9001:2000的单个条款。

3、分析和决定

a、全面地评价审核发现(使用风险评估/“常识”);

b、将审核发现与组织提供合格产品的能力(见ISO 9001:2000条款1.1)联系起来。

4、报告和追踪

a、敏锐地报告审核发现

I. 可以根据下列因素要求不同的方法:

- 组织的成熟度（1、2、3、4区）;
- 对组织QMS的信任水平;
- 相关的风险;
- 受审核方对审核过程的态度和承诺:
  - 主动;
  - 被动。

II. 确保考虑了所有的文化因素;

III. 适当时，强调正面的审核发现;

IV. 组织对负面发现提出的解决办法是否***有用***?

b、报告应当客观，并着眼于真正的“读者”（最高管理层的期望很可能与管理者代表不同）。

日期：2004 年 10 月 14 日

ISO 9001 审核实践组指南

对“能力”和“所采取措施的有效性”的审核

本文件用于指导认证审核员理解ISO 9001:2000条款6.2.2对“能力”和“所采取措施的有效性”的要求（所采取的措施如培训）。

这些要求通常都是在审核产品实现过程时来审核的，而不是孤立地对这些要求进行审核。但是，有些组织有单独的人力资源过程，在其中可以找到大部分所需的证据。

本文件介绍了组织为确保人员能力和评价所采取的用于满足能力需求的措施有效性而进行的典型活动，并对审核员应当寻找哪类证据提供了指南，必要时举例说明。

为满足ISO 9001:2000的能力/有效性要求，组织通常需要做几件事:

- 确定从事影响质量的工作的人员所需要的能力;
- 确定哪些已经在进行这些工作的人员已具备了所需要的能力;
- 决定还需要哪些进一步的能力;
- 决定怎样获得这些进一步的能力——人员培训(外部或内部的)、理论或实践培训、聘用有能力的新员工、指派现有的有能力的人员从事不同的工作;
- 人员的培训、聘用或重新安排;
- 评价为满足能力需求而采取的措施的有效性;
- 定期审查人员能力。

在整个过程中，标准要求组织保留教育、培训、技能和经验的适当记录。但是，ISO 9001:2000并没规定怎样建立这个过程或需要保留的记录的确切性质。

当审核组织符合能力要求的情况时，审核员通常会寻求下述方面的证据:

1．组织需要确定从事影响质量的工作的人员需要具有什么能力

指南——审核员的目标应当是确定组织是否采用了系统的方法来确定这些能力，并对该方法是否有效进行了验证。过程的结果可能体现为清单、登记表、数据库、人力资源计划、能力发展计划、合同、项目或产品计划等。

审核员可以先同最高管理者进行讨论，以确保他们理解对所需要的能力进行识别的重要性。通过这些讨论，还可能得到有关新的或变化的活动或过程的信息，这些新的或变化的活动或过程可能会导致组织内不同的能力要求。

在考虑新的投标或合同时，可能也需要对能力进行审查。审核员可以在相关记录中找到能力评审的证据。当分包方的活动会对过程和/或产品质量特性产生影响时，合同文件中可能包括能力要求。

在监督审核期间，审核员需要确定组织是否已经确定了新的或变化了的能力需求。

2．有能力的人员是否被安排在控制过程和产品的质量特性所需的工作岗位上?

指南——审核员应当验证组织通过某种形式的评价过程来确保能力要求与组织的活动相适应，以及挑选出的有能力的人员确实证明了其能力。这个过程还应当确保对所有的不足都采取了措施，并且人员的有效性得到了测评。审核员应当验证对质量有影响的活动是由选出的有能力

的人员完成的。整个审核过程中都有可能找到相关的证据，重点应当关注那些受人员影响较大的那些过程、活动、任务和产品。审核员可以检查组织的工作说明书、检测或检验活动、监视活动、管理评审记录，职责和权限的规定、不合格品记录、审核报告、顾客投诉、过程确认记录等。

3. 组织需要评价为满足能力需求而采取的措施的有效性

指南——组织可以通过一系列方法来评价所采取措施的有效性，包括角色扮演、同行评议、观察、审查评审培训和/或任职记录和/或面谈（具体实例可参见ISO 19011表2）。具体评价方法的适宜性取决于许多因素。例如，可以检查培训记录以验证成功举办了培训课程（但请注意，仅此一项不足以证明接受培训者具备了能力）。但是，在评价审核员在审核中的表现是否令人满意时，就不能采用这种方法，而是需要通过观察、同行评议、面谈等方法来评价。组织可能需要综合通过教育、培训和/或工作经验方面的证据来证明人员具备了能力。

4. 能力的保持

指南——审核员需要验证组织建立了某种形式的有效的监视过程，并根据该过程采取了措施。监视过程的方式包括持续的职业发展过程（就像ISO 19011中给出的例子）、人员及其表现的定期评价或对相关个人或小组负责的产品进行定期检验、检测或审核。能力要求的不断变化可能表明组织采取积极的方式来保持人员的绩效水平。

日期：2005 年 12 月 12 日

ISO 9001 审核实践组指南

审核法律法规要求

ISO 9001:2000 要求组织识别并控制**适用于其产品（包括服务）**的法律法规要求，而组织在其 QMS 内如何识别和控制这些要求则由组织自己决定。

组织应当证实自己正确地识别了适用于其产品/服务的法律法规要求，而且这些要求可以获得并易于检索。

审核员需要了解适用于受审核方 QMS 所涵盖产品/服务的通用及特定的法律法规要求。在审核准备阶段，审核组应当从内部或外部渠道获取法律法规要求的相关信息，这样可以使审核员对 QMS 在满足这些要求方面的适宜性进行判断。这些要求需要得到识别并整合到组织的资源管理和产品实现活动中。

在审核阶段，审核组应:

- 确保组织有用于识别、保持和更新所有适用法律法规要求的方法
- 在监视“过程输出”与要求的符合性时，确保这些法律法规的要求被当作“过程输入”。
- 确保组织能够恰当地证实与标准和法律法规要求的符合性。
- 如果在审核时有证据表明组织遗漏了有关法律法规要求的特定信息，审核员应当开具不符合项。
- 如果直接识别出了与这些法律法规要求的不符合，审核员也应当开具不符合项。

由于可能会产生责任问题，审核员应当避免声称什么样的法律法规要求适用于该组织的产品/服务，或者应当采用什么方法来满足这些要求。

只有识别出体系在与组织产品/服务相关的法律法规要求方面的缺陷或者直接违背法律法规要求的情况时，才应当开出不符合项。

当然，如果审核时恰巧发现了与其他法律法规（如健康安全、环境等）要求的不符合，审核组不应当忽略这个事实。审核组应当及时向受审核方进行通报，在有要求时，也要向审核委托方通报。

如果在审核之前、审核过程中或审核实施之后，审核员意识到有任何影响质量管理体系形象和可信性的故意的与法律的不符合（包括，比如，违反反不正当竞争法、违反劳动法、违反健康和安全或环境法规），那么应当以适宜的方式考虑这些不符合，并对其进一步调查。与监管部门的角色和行为不同，审核员应当评估质量管理体系在满足客户要求方面（明示或通常隐含）的有效性，并把评估结果报告给认证机构以便其采取适当的措施。

日期：2005 年 12 月 12 日

ISO 9001 审核实践组指南

对质量方针、质量目标和管理评审的审核

1. 审核质量方针

只有在审核的整体结论的基础上，才能真正对质量方针及其有效展开情况进行评审。

审核方法应包括:

- 与最高管理层面谈，了解其对质量的承诺和途径;
- 通过管理评审的记录，评价最高管理者的承诺和在建立、实施、监视和更新质量方针方面的参与程度;
- 评价管理层是否有效地将质量方针“翻译”成易于理解的话，并通过在各适当的职能／层次上确立相应的目标，将其变成在组织所有层次上的指导方针;
- 与员工面谈，验证他们是否有正确的意识和知识，理解组织的质量方针**与其本职活动的关系**，不必在意他们使用什么样的词汇来表达;
- 搜寻质量方针通过适当沟通进行有效传播的证据。

2. 审核质量目标

审核员需验证组织已规定了总的质量目标，质量目标反映了质量方针，并与总的经营目标（包括顾客期望）充分保持一致。如果不是，审核员应进一步评价最高管理者对质量的承诺。

质量目标的实现需要被测量和文件化。

质量目标的确定或文件化没有特定的方式，质量目标可以通过经营计划、管理评审输出、年度预算等来体现。审核员应证明质量目标被充分文件化。

审核员应获得证据表明，质量目标以什么方式在组织的整个机构和过程中适当展开，并连接总的战略目标直到管理目标，向下连接到具体的操作活动。

在审核过程中，建议在文件评审阶段就应检查文件化的质量目标。

在审核结束前，审核员应查证质量目标是现实的、恰当的，组织为实现目标向负责人员分配了所需的资源。此证据应在组织的各层次上获得。

质量目标不是一成不变的，需要随着当前的经营环境和持续改进的要求不断更新，审核组应验证组织的整体业绩是否反映了质量方针的目的，是否很好地实现了质量目标。

审核员应记住，目标的实现是能够以定量或定性的方式进行测量的，还应记住，在质量方针和质量目标的修订机制，以及组织持续改进的承诺之间应建立明确的联系。

3. 审核管理评审

ISO 9001: 2000要求最高管理层按照计划的时间间隔对组织的质量管理体系进行评审，以确保其持续的适宜性、充分性和有效性。管理层可以单独开会来进行评审，但这不是标准的要求。最高管理层可以通过很多方法来评审质量管理体系，比如听取并评审管理者代表或其他人员的报告，通过电子方式进行沟通或定期召开管理会议（在会上还可以讨论预算和目标这样的事项）。

管理评审是一个过程，管理评审的实施和对管理评审的审核都应当采用过程方法。

ISO 9001:2000 条款 5.6.2 规定了管理评审过程的输入，这些输入应作为管理评审的议题。但是，管理评审并不是只能包括这些方面。管理评审中可能不会逐一或同时讨论这些议题，而是作为对业务的总体评审的一部分来讨论。审核员应当意识到输入可以有很多形式，如报告、趋势图等等。

作为管理评审过程的输出，应当有以下决定的证据:

- 质量方针和目标的变化;
- 改进计划和可能的改进措施;
- 资源变化;
- 修订的业务计划;
- 预算。

输出不仅仅与改进或变化相关，也包括对其他重要事项作出的决定，如引进新产品的计划。

标准要求保留管理评审的记录，但并未规定记录的形式。会议纪要是最常见的记录，但电子记录、统计图表、演示稿等也是可被接受的记录形式。

管理评审过程还可以包括对过程和体系的做出考虑的质量管理体系策划的内容。在这种情况下，审核员应当审查下列方面是否已得到了考虑:

- 管理体系或业务的变化在整体上会对体系或业务的其他部分产生影响吗?
- 在实施所建议的更改前，对其进行评估了吗?
- 在编制战略计划时，是否考虑了诸如标准条款 4.1 中的问题?
- 在开始将一个过程外包前，是否识别了所需的控制?

管理评审过程不仅仅是为了满足标准和审核员的要求，还应该成为组织经营管理过程中不可分割的一部分。全面的管理评审是一个在组织各层面实施的复杂过程，是由最高管理层根据来自组织各个层次的输入而实施的一个双向过程。管理评审的活动可以是每天、每周或每月的会议，或是部门会议，也可以是简单的讨论或报告。

审核员应当寻找证据来证明管理评审过程的输入和输出与组织的规模以及复杂程度相关，并被用于业务的改进。审核员还应当考虑组织的管理层结构是什么样的，这个机构是怎样来运用管理评审过程的。

日期：2006 年 5 月 15 日

ISO 9001 审核实践组指南

审核监视和测量装置的控制

本文件为审核与监视和测量装置控制相关的过程提供了指南，这些指南可以有助于评价组织从质量管理体系范围中删减条款 7.6 是否合理。

在审核监视和测量过程时，审核员要理解“监视”和“测量”这两个概念之间的区别，这一点很重要:

- 监视指观察、监督、使对象处于检查之下（使用监视装置）；它可以包括定期测量或检测，特别是为了调节或控制而进行的定期测量或检测;
- 测量指对物理量、数量或尺寸的确定(使用测量设备)。

ISO 9000 条款 3.10.4 对“测量设备”定义如下: “为实现测量过程所必需的测量仪器、软件、测量标准、标准物质或辅助设备或它们的组合”，但 ISO 9001 标准仅要求在通过产品或过程的测量为“产品符合确定的要求提供证据”时，需要对“测量设备”进行校准。

设备和装置可以用于显示读数、监视或测量。所有这三种活动都可以使用相同的设备。

例如，某些行业可以将压力表用作:

- 读数指示器（例如用来确保保持压力）;
- 监视装置（例如用来确保压力稳定和过程受控）;
- 测量设备（例如压力的准确值对于产品质量很重要的情况）。

但是，控制的水平取决于产品的预期用途，并决定了是否应当对测量和监视装置进行校准或检定。这种确认的深度和程度可能因产品、服务和相关风险的性质而不同。

如果组织使用测量设备，审核中应当获取证据来证明组织已经正确地识别/规定了与生产和服务过程相关的计量要求，而且测量系统的设计、运行和维护方式可以满足适用的计量要求。

审核员应当确认组织除了提供必要的校准记录并保证相关测量的不确定度和溯源性外，还了解并实施了（适用时）ISO 10012 所述的计量确认系统，而且该系统相对于所作测量的程度和类型而言是充分的。

像旅馆、饭店、教育机构、咨询服务机构、公共服务机构这样的一些组织，根据其产品的性质，采用调查问卷、调查表、试卷、统计报告等作为“监视或测量装置”来实施监视和测量活动。

这些“装置”应当受控，并得到相应的确认，以确保它们作为过程、产品/服务及顾客满意度的监视和测量手段的一致性。

适宜的做法是在审核条款 8.2“监视和测量”的符合情况时，关注这些“装置”的受控情况。如果组织能够证明按照该条款对这些“装置”进行了适当的控制，审核员需要意识到，并非所有与条款 7.6 相关的要求都适用于这些“装置”。

审核员需要理解组织是如何实施过程控制的，以及通过这些“装置”获得的信息对上述过程控制的影响。

当通过“监视和测量装置”获得的信息对过程控制产生影响时，审核员应当评价以下方面:

- 组织怎样确认“监视和测量装置”与监视和测量要求保持一致;
- 组织怎样保证信息的确实和有效;
- 负责设计“监视和测量装置”的人员的能力;
- 组织怎样确认结果的一致性。

根据上述内容，组织应当能够决定是否可以删减条款 7.6 的全部或部分要求。其重点在于，仅仅因为组织没有需要校准的测量设备并不意

味着可以自动删减整个 7.6 条款的符合性；这样的删减要求其同时不需要监视装置和测量设备。

《ISO 手册：ISO/TC 176 对小型企业如何实施 ISO 9001:2000 的建议》提供了进一步的解释和示例。

日期：2004 年 10 月 14 日

ISO 9001 审核实践组指南

有效地使用 ISO 19011

ISO 19011:2002《质量和环境管理体系审核指南》代替了原来的 ISO 10011 质量管理体系审核系列标准，为第一方、第二方、第三方质量和环境管理体系审核提供了指南。该标准的大部分内容与第三方质量管理体系审核有关，但并不是所有条款都能直接适用于第三方审核。标准包含对审核方法和审核员能力的指南，但是这些指南不是强制性的。该指南具有灵活性，对指南的具体应用可以因受审核组织规模、性质和复杂程度的不同而不同。第三方审核机构要按照自己的需要和工作实践以适宜的方式使用指南。

该标准分为以下几个部分:

审核原则

审核员应当熟悉审核的五项原则，并在审核过程中应用这些原则。

审核方案的管理

对审核方案的管理是第三方审核机构管理人员的职责，而不是某个审核员的职责。审核员应当知道审核方案将受到监视，并将按适当的间隔受到检查。审核员应当为审核方案的改进提出建议。

审核活动

标准强调审核策划、实施、报告的重要性及其技术方法，该部分是与审核员最紧密相关的，审核员应当对指南 ISO19011 第 6 章审核活动的内容非常熟悉。

审核员的能力和评价

在审核员能力和评价方面，该标准对审核组能力和审核员个人能力的重要性给予了新的强调，代替了在 ISO 10011－2 规定的审核员资格准则。

现在的“能力”定义为：经证实的个人素质和应用知识与技能的本领。对教育水平、工作经历、审核经历和审核次数的限定已经不像原来那么重要了。现在将这些方面作为审核员能力所需的知识和技能的输入。

虽然标准中的大部分指南可供第三方审核机构制定本机构对审核员能力的准则，但是审核员个人也应当了解本章内容，以便审核员能够保持和提高他们的专业能力，并在他们的专业能力范围内进行工作。

标准还提供了一些实际的帮助，以及围绕各问题的案例、解释，但是有些可能不适用于第三方审核。

日期：2004 年 10 月 14 日

ISO 9001 审核实践组指南

审核顾客反馈过程

1. 引言

顾客反馈过程是质量管理体系的一个重要部分，在第三方审核中应给予充分关注。顾客的反馈是用于判断质量管理体系整体有效性的一个基本的绩效指标，所以审核员应当验证以下四个方面:

a) 组织的顾客沟通渠道提高对顾客反馈过程（顾客能够通过该过程提供反馈）的意识;

b) 顾客反馈过程的输入包括相关的、有代表性的和可靠的数据;

c) 对数据进行了有效分析;

d) 过程的输出为管理评审和其他质量管理体系过程提供了有用的信息，以提高顾客满意度并推动持续改进。

2. 标准的要求是什么?

2.1 ISO 9001:2000 的总目标（见条款 1.1）是“为有下列需求的组织规定了质量管理体系的要求:

a） 需要证实其有能力**稳定地提供满足顾客和适用的法律法规要求的产品**;

b） 通过体系的有效应用，包括体系持续改进的过程以及保证符合顾客与适用的法律法规要求，旨在**增强顾客满意**。”

2.2 ISO 9001:2000 条款 7.2.3 要求“组织应对以下有关方面确定并实施与顾客沟通的有效安排: ……c)顾客反馈，包括顾客抱怨。”

2.3 ISO 9001:2000 条款 8.2.1 规定:

“作为对质量管理体系业绩的一种测量，组织应**对顾客**有关组织是否已满足其要求的**感受**的**信息**进行**监视**，并确定获取和利用这种信息的方法。”

ISO／TC176 对 ISO 9000 术语的指南（ISO／TC176／SC2／N526R）强调**监视**的含意是“观察、监督、审查，定期测量或检测”。重要的是审核员要认识到，虽然进行正式的顾客满意度调查，或对顾客满意度进行其他测量，可以是组织对顾客感受进行监视的一种有用方法，但是 ISO 9001:2000 条款 8.2.1 对此并没有特别要求。因此，重要的是组织试图从顾客的角度看问题，并**监视顾客的感受**；对顾客**满意度**进行**测量**在一些情况下可能是适宜的做法，但并不是标准的直接要求。

注：整个标准中除了明确提到顾客反馈过程的要求外，还有一些间接提到顾客反馈过程的要求，也需要审核员考虑。例如，把反馈作为设计和开发过程、过程确认和其他活动的一部分。

3. 在审核顾客反馈过程时应当注意什么?

顾客反馈是一个**过程**。审核员需要把它作为一个过程进行**审核**，而不是作为标准的一个条款进行审核。审核员需要评价对过程进行管理的方式（见 ISO 9001:2000 条款 4.1.c），并评价过程提供用于判断 QMS **整体**有效性的有用信息的能力。组织获取反馈的方式由组织自己来确定。

审核员应当意识到有很多因素会影响组织采用的方式，并没有固定的模式。应当予以适当考虑的因素例如:

- 组织的规模和复杂程度;
- 产品的复杂或精密程度，以及顾客的成熟程度;
- 与产品有关的风险;
- 顾客群的多样性。

3.1　在审核顾客反馈过程之前的工作（准备阶段）

审核员需要了解组织产品的可能影响顾客满意度的具体特性。在整个审核中，审核员应当对可能暗示着顾客满意或不满意的迹象保持警觉，这些信息可以作为对顾客反馈过程进行审核的输入。此类信息的好的来源可能包括，例如:

- 顾客的退货;
- 顾客要求保修;
- 经过修改的发票;
- 信用记录;
- 媒体上的文章;
- 消费者网站;
- 直接观察顾客或直接与顾客沟通（例如在服务型组织）。

3.2 在对过程进行评价中

审核员在审核顾客反馈过程时应当关注下面一些问题:

a) 所期望的过程输出是什么？对于顾客感受，真正**能够得到**什么信息？管理者如何利用这些信息推动产品、过程和质量管理体系改进?

- 这些信息是否覆盖了所有的顾客类别？重要的是要记住组织可能有多类顾客（见 ISO 9000: 2000 条款 3.3.5 对“顾客”的定义）。例如一个制造商可能把产品卖给批发商，批发商再卖给零售商，零售商再卖给普通公众。在这种情况下，该组织可能需要关注所有这三类顾客，他们可能有不同的感受。组织可能使一类顾客满意，却使另一类顾客失望。

b) 收集到的信息**怎样**输入过程？

- 组织可能有多种方式来监视顾客的感受，审核员应当避免在该怎么监视顾客感受上先入为主。组织可以使用的方法例如:
  - 面对面的评价。很多服务型组织适宜使用这种方式，例如宾馆：“你和我们在一起感觉怎么样？”，或饭店：“我希望您用餐愉快。”
  - 定期地或在产品和服务交付后，进行电话回访或走访;
  - 组织亲自或委托独立的市场研究机构进行问卷调查;
  - 与顾客的其他联系，例如通过服务或安装人员;
  - 在组织内部询问与顾客有联系的人员;
  - 对重复发生的业务进行评价;
  - 对应收账目、保修索赔等进行监视;
  - 对顾客抱怨的分析。

顾客**自发**提供的反馈往往只是他们的抱怨。组织应当对顾客的抱怨进行分析，以从中发现趋势、关键问题和相关的影响等。但是，必须强调的是监视顾客感受时不能仅将顾客抱怨作为输入。审核员还应当避免只根据个别抱怨就做出结论，而应当评价这些抱怨对质量管理体系的整体影响。

c) 信息的可靠程度有多少？

- 在理想状态下，组织最好能监视所有的顾客的感受，但是这样做的成本可能过高。因此，审核员有必要验证组织对顾客的抽样准则，以确保组织抽取的顾客样本具有代表性，并且反映了组织及其顾客所承担的风险。
- 审核员应当将组织提供的信息与审核过程中获得的其他证据进行比较，以验证这些信息。

- 在一些情况下，审核员直接从组织的顾客那里验证相关信息，可能是一种适宜的做法。不过，这样做需要一定的交流技巧。

d) 信息是怎样分析的？

- 仅仅简单地收集顾客感受的信息是不够的，审核员必须贯穿整个过程，来检查组织是怎样对信息进行分析的（见 ISO 9001:2000 条款 8.4），以及在质量管理体系有效性方面得出了什么结论。
  - 有没有什么趋势？
  - 情况是稳定、正在改进还是正在恶化？
  - 顾客的需求和期望变化了吗？
- 虽然 ISO 9001:2000 没有要求，审核员还是可以向组织询问同行业内的比较情况或比对活动，以便全面地考虑顾客反馈。

e) 怎样将顾客反馈过程产生的信息作为一个整体反馈到质量管理体系中？

- 组织应当用顾客反馈过程的结果来启动纠正和／或预防措施，并作为对质量管理体系绩效进行整体测量的一个方面。审核员还应当对这些过程之间相互作用的方式进行审核。
- 审核员应当能够认识到，顾客反馈过程的输出构成了其他质量管理体系过程的一个重要输入，例如数据分析、管理评审、持续改进等过程。
- 致力于提供增值的审核员会试图使组织认识到良好的顾客反馈过程可以带来的好处，并将鼓励(但不能要求)组织超越仅仅“满足标准的要求”进行思考。

f) 与其他质量管理体系过程有什么联系？

- 审核员应当认识到，顾客反馈过程与其他一些质量管理体系过程之间有重要的联系和接口，这些质量管理体系过程包括但不限于以下标准条款:

  -5.6 管理评审

  -7.5.2 过程确认

  -7.2.3 顾客沟通

  -7.3.6 设计和开发确认

  -7.3.7 设计和开发更改

日期：2005 年 2 月 10 日

ISO 9001 审核实践组指南

开具不符合项

任何管理体系审核的关注点都是确定组织是否建立、有效实施并保持了管理体系。组织只有有效地实施了符合 ISO 9001:2000 要求的管理体系，才能获得认证。所以，管理体系审核的重点应当是验证其符合性，而不是开具不符合项。

审核员应当采取积极的方式来寻找事实而不是挑错。但是，当审核证据表明存在不符合，那么正确地开具不符合项就重要了。

什么是不符合？根据 ISO 9000:2000 条款 3.6.2 的定义，“不符合”是“**未满足要求**”。

开得比较好的不符合项包括三部分:

- 为审核发现提供支持的**审核证据**;
- **记录**判定不符合所依据的**要求**;
- **对不符合的陈述**。

在实践中，虽然不符合项要包括上述所有部分，但审核员首先要确定和记录审核证据。这是因为有能力的审核员在审核中会观察到使他“感觉”可能是潜在不符合的情况，尽管当时他可能不能 100%确定。在追踪进一步的审核线索之前，有能力的审核员会在自己的审核笔记上记录关于潜在不符合的审核证据，以便确认它是否确实是不符合。

如果**没有**审核证据——就**不存在**不符合。如果**有**证据——就**必须**开具不符合项，而不是将其软化处理为其它类型的问题（如“观察项”、“改进机会”、“建议”等）。从长远看，这种软化处理对组织、组织

的顾客和认证机构都没有好处，因为这会引起不重视不符合、不认真采取纠正措施的风险。

审核证据应当形成文件并足够详细，以便能使受审核组织精确地查找和确认审核员所观察到的问题。

审核员下一步需要确定和记录未得到满足的特定要求。记住，不符合是未能满足要求，所以审核员只有识别出未被满足的要求，那才能开出不符合项。

要求的来源可能有很多：例如， ISO 9001:2000 的规定要求、组织管理体系的要求（内部要求）、适用的法规要求、或组织顾客的要求。一旦审核员依据特定要求确认了不符合，就需要记录不符合。这种记录可以比较简单，比如引用标准和相关条款。

（注：ISO 9001 的有些条款包含了多项要求。因此审核员要清楚地识别和记录与不符合有关的那项要求，这一点很重要。比如写下中标准适用于审核证据的那项要求的原文。对其他来源的要求也可以这么做。）

开具不符合的最后一步（也是最重要的一步）是陈述不符合。**不符合的陈述促使组织进行原因分析、采取纠正和纠正措施**，所以它需要精确。

对不符合的陈述应当：

- 清楚明确并与体系的问题相关；
- 没有歧义、语言准确并尽可能简练；
- 不是审核证据的重述或复述。

总之，开具得较好的不符合项将有下列三个部分：

- 审核证据；
- 要求；
- 不符合的陈述。

如果审核员较好地填写了不符合项的所有三个部分，那么受审核方或其他有知识的人将能够阅读和理解不符合项。这还可以作为供今后参考的有用记录。

审核员以系统的方式记录和开具不符合，对提供可追溯性、便于进行审查并为纠正措施地完成提供证据来说必不可少。做到这一点的一个简单的方法是使用不符合项报告(NCR)表格。下面的附录A给出了一个不符合报告表格的示例。

附录 A　不符合报告（NCR）表格的示例

<table>
<tr><td>不符合编号:</td><td>客户:</td><td></td><td>档案号:</td><td></td></tr>
<tr><td>职能/区域/过程:</td><td></td><td>场所:</td><td></td><td></td></tr>
<tr><td>标准和条款号:</td><td colspan="4"></td></tr>
<tr><td colspan="5">第 1 部分 – 不符合的详细内容:</td></tr>
<tr><td colspan="5">描述</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td>审核员:</td><td></td><td rowspan="2">受审核方代表确认:</td><td colspan="2" rowspan="2">类别:</td></tr>
<tr><td>日期:</td><td></td></tr>
<tr><td colspan="5">第 2 部分 – 受审核方提出的措施计划（可另附页）</td></tr>
<tr><td colspan="5">根本原因分析（怎样发生的/为什么发生?）:</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="5">纠正（即时改正）及完成日期:</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="5">纠正措施（防止再发生）及完成日期:</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="5">审核员对纠正措施计划的审查和接受情况:</td></tr>
<tr><td>受审核方代表:</td><td colspan="2"></td><td>日期:</td><td></td></tr>
<tr><td colspan="5">第 3 部分 – 审核员对受审核方措施计划实施情况进行验证的详细内容</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="2">第 4 部分-审核员关闭 NCR 的日期:</td><td colspan="3">审核组长姓名:</td></tr>
<tr><td colspan="2"></td><td colspan="3"></td></tr>
</table>

日期：2005 年 2 月 10 日

ISO 9001 审核实践组指南

对审查和关闭不符合项的指南

介绍

审核员对组织对不符合项的答复和组织对不符合项采用的“关闭”过程进行审查，有可能增加审核为组织提供的价值，也可能降低这一价值。如果审核员确保组织已经令人满意的进行了纠正，分析了不符合的原因，并采取了纠正措施，那么就会增加审核的价值，因为这样将增大组织赢得顾客满意的可能性。

本文件针对审核中发现的不符合项的审查和关闭过程提供了指南，以帮助审核员。

审查对不符合项的答复和措施

管理体系审核员负责审查对不符合项的答复，并验证所采取措施的有效性。

组织对不符合项的答复应当包含三个部分:

- 纠正
- 原因分析
- 纠正措施

或

- 原因分析
- 纠正
- 纠正措施

（注: 上面给出了两种不同的排列顺序，这是因为需要根据产品的类型或者不符合的具体情况选择正确的顺序。但是，在每种情况下，不符合的解决的这三个部分都是一样的。例如，对于软件，直到找到了原因再去进行纠正是失策的做法。相反，再举个硬件产品的例子，如果汽车里“刹车片不足”的警示灯亮了，你没有先去看看是不是警示灯的传感器出了问题，就立即通过更换刹车片进行纠正，那么你可能解决不了问题，而且还会浪费时间和资源）

ISO 9000: 2000 对不符合、纠正和纠正措施作出了权威的定义:

不符合: 未满足要求（ISO 9000:2000 条款 3.6.2）

纠正：为消除发现的不符合采取的行动（ISO 9000:2000 条款 3.6.6）

纠正措施：为消除发现的不符合或其他不期望情况的原因而采取的行动（ISO 9000：2000 条款 clause 3.6.5）

在发现不符合时，既需要进行纠正，也需要采取纠正措施。

“纠正”是消除发现的不符合的行动。例如，纠正可能包括用合格产品替换掉不合格产品，或者用程序的当前版本替换过期的版本，等等。

“纠正措施”的定义是“消除发现的不符合的原因的行动”。要采取纠正措施，就必须先确定不符合的原因。一个组织可以采用很多方法和工具来确定不符合的原因，从简单的头脑风暴到更为复杂的解决问题的系统方法（例如根本原因分析、鱼刺图、“五个为什么”等等）。审核员应当熟悉如何正确使用这些工具。纠正措施的程度和有效性取决于是否能找到真正的原因。在一些情况下，这将帮助组织找到另一区域的相似的不符合，并使之最小化。

在审查组织对不符合的答复时，审核员在接受组织的答复前，应当确认组织对所有三个部分——纠正/原因分析和纠正措施——都提供了相关的文件和**客观证据**，并且这些文件和证据是适宜的。审查过程中要验证的重要方面包括：

- 对措施的说明；是否清晰和简练？
- 对措施的描述；是否详尽，并且准确引用了相应的具体文件或程序等？
- 使用过去时态（was，has or have been，were）来表示所采取的行动已经完成。
- 完成纠正措施的日期；应当查看纠正措施的日期是否是过去的一个时间，表明已经采取了纠正措施（在将来的日期采取纠正措施

不是好的做法）。

- 为已完全和有效地实施了纠正措施，并按照所描述的方式实施了纠正措施的声明提供支持的证据。

此外，审核员应当验证组织已确保纠正措施本身不造成产品质量或QMS实施方面的进一步的问题。

应当注意，既采取纠正又采取纠正措施并非总是适宜的，可能仅进行纠正或者仅采取纠正措施本身就已经足够了。可能发生这样的情况的例子如，不符合项被证明纯粹是偶然发生的，再发生的概率非常低。

有效的纠正措施应当通过消除不符合的原因防止不符合的再发生。但是，纠正措施不应当与预防措施混淆。预防措施的定义是:

预防措施：消除**潜在**的不符合或其他不期望情况的原因的行动（ISO 9000:2000条款3.6.4）

应当注意，预防措施，就像其定义描述的那样，不适用于已经发现的不符合。但是，通过分析已经发现的不符合的原因，有可能找到组织其他区域更大范围内的潜在不符合，并为预防措施提供输入。

关闭不符合

由于不符合在性质上倾向于是个别的，可以使用不同方法或活动来关闭不符合。例如，有些需要到现场直接进行检查（可能要求再追加现场访问），而其他可以远程关闭（通过审查所提交的文件化证据）。

在做出同意关闭不符合的决定之前，审核组长（如果仅有一个审核员，则指该审核员）应当审查组织在纠正/原因分析方面做了哪些工作，以及纠正措施取得了什么结果。审核组长/审核员需要确保有客观证据（包括支持性文件）证实所描述的纠正措施已得到了完全的实施，并有效防止了不符合的再发生。只有在这些方面令人满意后，才应当关闭不符合。

日期：2005 年 2 月 10 日

ISO 9001 审核实践组指南

对内部沟通的审核

1. 介绍

有效的内部沟通过程有助于组织质量管理体系的成功。相反，组织质量管理体系中的许多问题常常可以从沟通方面的**不足**找到原因。

2. 要求和指南

2.1 ISO9001:2000 条款 5.5.3 规定如下:

“内部沟通”

“最高管理者应确保在组织内建立适当的沟通过程，并确保对质量管理体系的有效性进行沟通。”

如果简单地以“是”或“否”来判定组织是否符合这一要求，对于评价组织内部沟通过程的有效实施可能是不充分的。ISO 9001:2000 中的其他许多要求也是如此。

2.2 ISO 9001:2000 关于内部沟通的其他要求:

ISO9001: 2000 还要求最高管理者有责任与组织内的人员在以下方面进行沟通:

- 质量方针和质量目标;
- 满足顾客和法律法规要求的重要性;
- 提高整个组织的顾客要求意识;
- 人员的职责，对自己活动的意义和重要性的认识，以及怎样为实现质量目标发挥作用;
- 产品要求变更时，确保相关人员知晓变更后的要求。

2.3 ISO 9004:2000 的指南（条款 5.5.3）:

“组织的管理者应当规定并实施一个有效和高效的过程，以就质量方针、要求、目标和实现情况进行沟通。提供这些信息有助于组织的业绩改进，并有助于使组织的人员直接参与实现质量目标。作为一种使组织的人员充分参与的手段，管理者应当积极鼓励来自他们的反馈和沟通。”

审核员不能依据 ISO 9004 的上述指南进行审核（这一点很重要，应当注意），但它的确有助于我们理解和认识内部沟通。

3. 验证内部沟通的有效性

对于 ISO 9001:2000 条款 5.5.3，必须验证下面两个主要部分:

a) 组织内部已经**建立**了适当的沟通过程，包括:

- 确定哪些人员之间需要进行沟通;
- 需要沟通的信息;
- 实现沟通的手段;
- 沟通有效性的监视方法;
- 证明已进行了沟通的必要文件和记录;
- 对沟通过程的持续改进。

b) 沟通正在进行，**并与质量管理体系的有效性相关**。

审核员在寻找沟通过程有效性的证据时，可能需要根据受审核组织的具体情况，对下列所有方面或其一部分进行观察:

- 组织的最高管理者、各级员工和分包方提出、接收沟通信息和对沟通信息做出响应的情况;
- 需要沟通的信息相对于沟通目的而言是否明确、适当和准确;
- 沟通所使用的方式，是否与沟通对象（那些被期望接收沟通信息并对之做出反应的人）的文化水平和其他技能相适应;

- 对沟通过程进行了监视，以确保依据所沟通的信息采取行动并达到预期的结果;
- 具有证实沟通已经进行并且有效，并得到持续改进的必要的程序和记录。

尽管标准没有专门要求制定形成文件的沟通程序，但组织可能有必要根据自己的规模、复杂程度和文化，制定确保内部沟通的有效实施的程序文件。

4. 审核员的方法

审核员可以对以下组织内部信息沟通的手段的全部或一部分进行观察:

- 在工作区域由管理者主导的沟通;
- 小组内部的简短沟通和其他会议，例如对成绩做出肯定的会议;
- 通知和公告;
- 电子邮件、局域网和网站;
- 公司对外或对内散发的杂志、工作通讯;
- 员工会议;
- 单独的通知或信件。

审核员可以通过以下方式判断组织内部沟通过程的有效性:

- 与员工进行面谈，以确定他对方针、目标和管理体系绩效的认识;
- 评估不符合的原因和组织的纠正措施过程，确定能否将纠正措施需求追溯到内部沟通过程的不足或与之联系起来;
- 评估沟通信息的相关性和重要日期。如果沟通的信息过时，则毫无价值;

- 检查组织的内部反馈机制，例如一对一的面谈或讨论，员工调查等;
- 评价组织的培训计划和新员工培训计划。这些计划中应当包含关于质量管理体系如何运行的信息;
- 查看包含内部沟通议题的会议纪要。

5. 评价组织符合 ISO 9001:2000 要求的情况

如果一个审核员在审核过程的一个区段或一个时间段内就能确定组织内部沟通过程的有效性，这种做法是令人怀疑的。对内部沟通过程有效性的审核应当贯穿整个审核活动，采用更有整体性的方法，但不一定在审核计划中作为一个单独的项目。审核组应当策划如何来协力完成对内部沟通过程有效性的审查。

与此相似，仅根据组织内的一面之词就确定组织内部沟通过程是有效的，这种做法也是令人怀疑的。

审核组只有在审核活动结束时，对审核证据进行评价（并且在审核组成员之间达成一致）后，才应当确定组织是否符合 ISO 9001:2000 的要求。

日期：2005 年 2 月 10 日

ISO 9001 审核实践组指南

对预防措施进行审核

1. 引言

ISO 9000:2000 条款 3.6.4 对“预防措施”的定义是“为消除潜在不合格或其他潜在不期望情况的原因所采取的措施”。

我们可以将预防措施理解成为防止不符合发生而采取的措施。不过，如果没有不符合，而且预防措施有效，那么预防措施过程的预期输出将是“维持现状”，这种输出增加了预防措施过程的审核难度。

人们经常混淆纠正、纠正措施和预防措施（正式定义参见 ISO 9000:2000）三个术语之间的区别，以及组织与它们有关的活动。

对组织的纠正和纠正措施过程进行审核相对比较简单，因为通常能够比较好地确定这些过程的结果和有效性（即如果组织识别出了不符合，那么审核员去评价组织已经采取或计划采取的纠正过程，以及该过程是否将有效避免不符合再次发生，就相对简单一些）；但是，对预防措施过程的审核通常较为复杂。

2. 审核指南

2.1 ISO 9001:2000 要求组织制定形成文件的预防措施程序。

注：将纠正措施和预防措施的文件化程序合并在一份 QMS 文件中的做法是可以被接受的，但我们并不推荐这种做法。如果两者合在一起，审核员应当验证组织是否清晰地理解纠正措施和预防措施的不同用意，这一点很重要。

2.2 标准要求形成文件的预防措施程序包括:

a) **组织怎样确定潜在的不符合及其原因**

典型的例子包括:

- 过程和产品特性的趋势分析（数据分析过程的输出）。如果趋势在恶化，就说明如果不采取措施，就会出现不合格;
- 在运行条件接近“失控状态”时发出预警;
- 通过正式或非正式的反馈系统监视顾客的感受;
- 使用统计技术进行过程能力趋势分析;
- 持续进行过程和产品的失效模式及后果分析（FEMA）（例如这是汽车行业 TS 16949 的要求）;
- 对相似情况下发生在其他产品、过程、组织的其他部分或其他组织的不符合进行评估;
- 针对可预见的情况（例如因扩张、维护或人员变化而出现的情况，又见 ISO 9001 条款 5.4.2.b）和不可预见的情况（例如飓风、地震、洪水等自然灾害）制定计划;
- ISO 9004:2000 条款 8.5.3“损失的预防”提供了其他示例(注: ISO 9004 的指南不是强制性要求）。

b) 评估对预防措施的需求

评估方法可以包括:

- 风险分析方法;
- 失效模式及后果分析，就上面（a）所述。

（注: 这些特定的方式或方法不是 ISO 9001:2000 的要求。）

c) 组织怎样确定需要采取措施以及怎样实施

审核员应当寻找下列证据:

- 组织已经分析了潜在不符合的原因（使用因果图和其他质量工具可能是适宜的）;
- 及时在组织的所有相关部分布置了所需的措施;
- 对识别、评价、实施和审查预防措施的职责做出了清晰的界定;

d) **所采取措施结果的记录**

- 保存了什么记录?
- 记录是否适宜，是否真实反映了结果?
- 是否按照 ISO 9001:2000 条款 4.2.4 对记录进行了控制?

e) **审查所采取的预防措施**

- 措施是否有效（即是否防止了不符合的发生以及是否有进一步的益处）?
- 有无必要继续采取正在实施的预防措施?
- 是否应当改变预防措施，或是否有必要策划新的措施?

2.3 审核员和组织之间经常会对纠正措施和预防措施之间的界限进行“理论上的”讨论。例如，如果在过程“A”中发现了不符合，那么为防止以后在过程“B”、“C”和“D”中发生此类不符合而采取的措施到底是预防措施还是对过程“A”采取的纠正措施?审核员应当避免被这些讨论误导，而应当关注这些措施是否有效。所采取措施的到底应该贴什么“标签”是次要的!

日期：2005 年 7 月 30 日

ISO 9001 审核实践组指南

对服务型组织的审核

1. 介绍

虽然 ISO 9001:2000 的目的是适用于各类组织，不论其类型、规模如何或提供什么产品，但是第三方审核中需要对服务型组织的一些特性予以特别关注。因此，本文件旨在为审核员审核服务型组织对 ISO 9001:2000 要求的符合性提供指南。本文件特别强调了条款 7.3“设计和开发”、7.5.2“生产和服务提供过程的确认”和 8.3“不合格品控制”的要求。

2. 服务型组织

按照 ISO 9000:2000 条款 3.4.2“产品”：

“服务通常是无形的，并且是在供方和顾客接触面上至少需要完成一项活动的结果。服务的提供可涉及，例如:

— 在顾客提供的有形产品（如维修的汽车）上所完成的活动;

— 在顾客提供的无形产品（如为准备税款申报书所需的收益表）上所完成的活动;

— 无形产品的交付（如知识传授方面的信息提供）;

— 为顾客创造氛围（如在宾馆和饭店）。”

大多数组织的产品中都包括服务的部分，从几乎 100%都是服务（例如法律事务所），到较小比例的服务，例如制造业组织提供的售后服务。

3. 审核指南

3.1 服务的设计和开发

在考虑 ISO 9001:2000 条款 7.3 是否适用于一个服务型组织时，重要的是要记住“设计和开发”的定义。按照 ISO 9000:2000 条款 3.4.4，“设计和开发”是“将要求转换为规定特性的一组过程”。而按照 ISO 9000:2000，“**要求**”（3.1.2）是“明示的、通常隐含的或必须履行的需要或期望”，服务的“**特性**”（3.5.1）是可区分的特征，可以包括:

- 感官特性（如：与嗅觉、触觉、味觉、视觉、听觉有关的）；
- 行为特性（如：礼貌、诚实、正直）；
- 时间特性（如：准时性、可靠性、可用性）；
- 人体工效特性（如：生理特性或与人身安全有关的特性）；
- 有形特性（如：可测量的特性；这些特性可能是提供服务的物质手段的特性，如飞机的最高速度，也可能是服务提供环境的特性，如飞机的内部温度或设施）。

组织在对待条款 7.3 的要求时，常常只考虑产品的实物部分，而忘了非实物产品（即服务）的设计和开发才应当是主要的关注点。另外，组织还需要设计向顾客提供服务。

如果组织提出从质量管理体系中删减设计和开发，审核员应当根据上述指南仔细评价删减的理由。审核员还应当检查组织是否建立了有效的设计和开发过程，来充分地定义满足顾客需求和期望所需的服务特性和服务提供过程特性。

3.2 生产和服务提供过程的确认

对于实现服务所需的过程，我们可以识别两种类型的服务过程:

- 顾客参与服务本身的实现（实时交付）；
- 过程实现后，才将输出交付给顾客。

以旅馆为例，客人的“登记入住”和“退房”过程很可能涉及“实时”的服务交付，而客房整理通常在过程（该过程可能要接受检查，必要时还需返工，以纠正所有不符合）完成后，才“交付”给客人。

在提供与其产品有关的服务的制造业服务中也可能发现类似的过程，例如处理投诉和保修，组织的服务部门对产品进行维修，或者在客户场所进行产品维护活动。

对于那些包含实时交付并在组织/顾客接口直接实施的过程，（如果有的话），很少有可能在它们的输出（“服务”）“交付”顾客前，用后续的监视或测量对这些输出进行验证。因此，这些过程确实应当按照 ISO 9001:2000 条款 7.5.2 的要求得到确认。这对**防止**不符合的发生也是必不可少的。

为了确保所提供服务的质量得到充分控制，审核员应当:

- 理解组织所规定的服务特性、服务提供过程及其接收准则（应当在第一阶段审核中理解）;
- 确定组织是否对“实时”服务提供过程（或其他需要确认的过程）进行了确认，以及确认时是否考虑了相关的风险;
- 评价组织是否向有关人员提供了适当的工具、培训和授权。

对于很多服务行业来说，所提供的服务是瞬间完成的（即通过“实时”过程），很难在服务的交付进行检验。从质量的观点来说，最经济有效的经营方式就是对这些服务应用“特殊过程”的原理：组织的过程越正确，就越不必担心过程的输出。因此，很少有可能删减这一条款。

3.3 不合格品控制

对于顾客直接参与的服务过程，“不合格品控制”（条款 8.3）是指组织在确定和实施正确的纠正措施之前对服务提供中的不符合进行处理的方式。

当识别出不合格时，审核员应当检查:

- 相关人员是否得到充分授权，因而有权决定对服务的处置，例如:
    - 立即终止服务;
    - 更换所提供的服务;
    - 提供替代方式;
- 组织的顾客索赔和投诉过程;
- 为减轻不合格的后果而临时采取的纠正（例如退款、赊账、升级等）
- 对相关服务设备、服务提供者及环境的识别、隔离和更换。

这将使审核员能够判断对不合格产品的控制是否有效。

注: 对于这些情况,质量管理体系应当规定在适当的管理层次采集关于不符合的数据，并进行信息反馈，以有效地制定和实施纠正措施。

对于在过程实现后交付服务的输出的情况，可以根据通常的监视和检验技术来进行“不合格品控制”。审核员需要搜集这些技术的充分性、适宜性以及得到有效实施的证据。

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ISO 9001 审核实践组指南

第三方审核员的公正性和利益冲突

审核员的公正性和客观性是有效、一致的审核的基本前提条件。

本文件阐述了确保审核员公正性的良好实践，供审核员以及负责评价审核员行为的机构（即认证机构和认可机构）参考（又见 ISO PAS 17001）。

1. 范围

1.1 第三方认证的总体目标是为依赖认证的所有各方提供信心。建立信心的主要原则是以在独立、公正和有能力的方式行事，并表现出这种独立性、公正性和能力。

1.2 本文件仅关注对审核员独立性和公正性的威胁，以及相应的保障。

2. 认证机构对公正性的承诺

2.1 认证机构宜通过组织结构和程序来证实其如何满足公正性的基本要求。

2.2 认证机构宜通过政策、程序和培训，来证实其如何应对那些可能（或有合理理由认为可能）损害审核员客观性的压力和其他因素。这些压力或因素可能产生于多种活动、关系和其他情况，也可能源自审核员的个人素质和性格特征。

3. 对审核员公正性的威胁

3.1 对审核员公正性的威胁是指可能产生偏见的根源，这种偏见可能（或有合理理由认为可能）损害审核员给出客观的审核意见和结论的能力。

由于这些威胁可能（或有合理理由认为可能）损害审核员给出客观的审核意见和结论的能力，认证机构宜识别和分析这些威胁的后果。

3.2　这些威胁是由各种活动、关系和其他情况造成的。为了认识威胁的性质及其对审核员公正性的潜在影响，认证机构宜识别特定活动、关系或其他情况所造成的威胁。下面列举了几类可能影响审核员公正性的威胁。

这些分类可能会有交叉，也没有囊括所有的威胁，但阐述了认证机构在分析审核员独立性和公正性时需要考虑的多类威胁。

- 自身利益的威胁——此类威胁源于审核员依其自身利益行事。自身利益包括审核员在情感、金钱或其他方面的个人利益。审核员可能自觉或不自觉地优先考虑他的自身利益，而不是他在实施质量体系审核中的利益。例如，客户向认证机构交费，使认证机构相对于客户有经济方面的自身利益。又如，审核员在受审核方有股份，会使他相对于受审核方有经济方面的自身利益；如果审核员的家庭成员受雇于受审核方，审核员相对于受审核方可能会有情感或经济方面的自身利益。
- 自我评审的威胁——此类威胁源于审核员评价自己或同事所做的工作。客观地评价自己或自己单位的工作可能比评价其他人或其他单位的工作要困难得多。因此，在审核员审查自己或同事所作的判断或决定时，可能会产生此类威胁。
- 熟识（或信任）威胁——此类威胁源于审核员受到与受审核方密切关系的影响。如果审核员不能对受审核方的言论持充分的怀疑态度，而且由于对受审核方的熟悉与信任而轻易认同受审核方的观点，就会出现此类威胁。例如，在审核员与受审核方有着非常密切或长期的个人或工作关系时，就有可能产生此类威胁。
- 胁迫的威胁——此类威胁源于审核员遭到（或认为遭到）受审核方或其他利益相关方的公然或暗中要挟。例如，审核员或认证机构与受审

核方发生分歧时，受审核方以更换审核员或认证机构相要挟，就可能产生此类威胁。

- 争辩的威胁——例如，认证机构或其人员在争端或诉讼中支持或反对某受审核方，而该受审核方同时也是他的顾客。
- 竞争的威胁——例如，认证机构的兼职审核员和受审核方在某项业务上是竞争对手。

4．审核员公正性的保障

4.1　认证机构应采取保障措施以减轻或消除对审核员公正性的威胁。保障措施可以包括禁令、限制、信息披露、政策、程序、规范、标准、规则、制度安排和环境条件。认证机构宜定期审查保障措施以确保其持续适用性。

注 1: 保障措施存在于审核的实施环境中，也可以为了应对不同活动、关系和其他情况所造成的威胁，由独立的决策者下令实施。保障措施的描述方法之一是根据其存在方式。

4.2　存在于审核实施环境中的保障措施的例子包括:

- 认证机构和审核员对其名誉的重视;
- 认可机构对认证机构公正性的评审和监督;
- 认证机构的委员会和法人治理结构（例如董事会）对公正性的监督;
- 法人治理的其他方面，包括认证机构在认证过程和审核员公正性方面的组织文化;
- 约束审核员行为的规则、标准和职业行为规范;
- 认可机构和（或）IAF 以及其他方面采取的处罚措施，以及这种处罚的可能性;
- 认证机构的法律责任。

4.3　存在于认证机构管理体系之中的保障措施的例子:

- 认证机构的组织文化强调审核员在行事时应考虑更广泛的利益，强调良好审核和审核员公正性的重要性;
- 认证机构的专业氛围和组织文化鼓励所有人都行为公正;
- 认证机构管理体系中关于保持审核员公正性的政策、程序和规范;
- 认证机构的其他政策、程序和规范，例如人员轮换、内部审核、技术方面的内部协商等方面的规定;
- 认证机构关于人员聘用、培训、升级和奖励的政策、程序和规定强调审核员公正性的重要性,审核员公正性在不同情况下面临的潜在威胁,以及审核员在对待一个特定的客户时，需要在考虑现有的减轻或消除公正性威胁的保障措施的基础上，评估自己相对于该客户的公正性。

4.4 保障措施的另一种描述方法是根据其特性。例如:

- 预防性措施——例如，在新聘用审核员的初任培训中强调公正性的重要性;
- 针对特定情况的措施——例如，禁止审核员的家庭成员与认证机构的客户之间存在某种雇佣关系;
- 惩罚性措施——例如，认可机构一旦发现不公正的行为就立即暂停或撤销认可资格。

4.5 也可以根据保障措施对可能威胁审核员公正性的活动或关系的限制程度来描述保障措施，例如禁止审核员向他所审核的客户提供咨询。

4.6 认证机构在评价审核员的公正性时宜考虑:

- 可能（或有合理理由认为可能）导致审核员的不公正行为的压力和其他因素——这里称作对审核员公正性的威胁;
- 可能减轻或消除这些压力和其他因素的后果的控制措施——这里称作审核员公正性的保障措施;
- 这些压力和其他因素的严重程度，以及这些控制措施的有效性;

- 在考虑控制措施有效性的基础上，这些压力和其他因素（或有合理理由认为可能）对审核员保持公正审核行为的能力造成损害的可能性。

5. 公正性风险水平的评估

认证机构宜通过考虑公正性威胁的类型和严重程度以及保障措施的类型和有效性，来评估公正性风险的水平。这一基本原则说明了认证机构在识别和评估由不同活动、关系和其他情况引发的公正性风险的水平时宜采用的过程。

注 1: 公正性风险的水平可以表示为从“零风险”到“最大风险”的连续区间上的一个点。公正性风险水平的整个区间可以划分为若干区域，各个区域分别表示客观性受到损害的各种可能性，如下表所示:

表 1——公正性风险的水平

零风险	轻微风险	有一定风险	高风险	最大风险
客观性不可能受到损害	客观性不太可能受到损害	客观性有可能受到损害	客观性很可能受到损害	客观性肯定会受到损害

客观性受到损害的可能性递增 →

注 2: 虽然不可能精确衡量特定活动、关系和其他情况对审核员公正性造成的威胁的风险水平，但可以用公正性风险区间中的某个区域表示。

6. 确定公正性风险水平的可接受程度

6.1 认证机构宜确定公正性风险水平是否处在公正性风险区间中可接受的位置上。认证机构宜评估特定活动、关系和其他情况引发的公正性风险的可接受程度。这种评估需要认证机构判断相关保障措施能否消除或充分减轻这些活动、关系和其他情况对公正性造成的威胁。如果现有措施不能消除或充分减轻相关威胁，认证机构宜决定需要增加哪些保障措施（包括禁令），以将风险和客观性受到损害的可能性降至可接受的水平。

6.2 考虑到审核实施环境中的某些因素——例如，审核员是由受审核方付费的——公正性风险不能完全被消除，因此，认证机构总要承担一些

公正性风险。但是，当存在公正性风险时，认证机构宜只接受很低的风险水平。只有这种很低的客观性受到损害的可能性，才符合审核员公正性的定义和目标。

6.3　某些对审核员公正性的威胁可能仅影响认证机构中的部分人员或群体，某些威胁的严重程度可能因不同个人或群体而异。为确保风险处于可接受的低水平上，认证机构宜识别这些威胁所影响的个人或群体，以及威胁的严重程度。认证机构可能需要根据不同个人或群体在审核中的作用而采取不同的保障措施。

6.4　认证机构宜确保通过增加保障措施降低公正性风险所带来的收益大于采取这些措施的成本。虽然收益和成本经常是难以确定和量化的，认证机构在决定审核员公正性方面的问题时还是应当加以考虑。

注：保持审核员公正性的成本由各方共同承担。有些是设计、保持和执行保障措施的直接成本，包括认证机构在公正性方面的质量控制成本、认可费用和审核员公正性自律的成本。还可能有其他的间接成本，有时称作“负面效应”或“非预期后果”，这些成本可能来自审核质量下降，或者因禁止或限制审核员的某些活动和关系而产生的其他负面结果。例如，认证机构限制审核员从事咨询或培训活动，可能会降低该机构对审核员的吸引力，导致审核质量的降低。保持审核员公正性的直接或间接成本可能受很多参数的影响，包括组织中受到保障措施影响的人数。由于审核员公正性的重要性不仅在于公正性本身，而且在于帮助实现更广泛的公共利益目标，因此认证机构宜考虑那些超出公正性保障措施的直接影响的负面效应或非预期后果。

7.　组织结构

7.1　除上述方面外，保护审核员公正性还需要与认证机构的组织结构结合起来，以确保所需保障措施得到实施。认证机构的组织结构宜能够向了解情况的、没有利害关系的第三方证实认证机构的公正性。

7.2　认证机构用于实现以上目标的组织结构宜透明，并为设计和实施用于实现以上目标的过程提供支持。这些过程应包括：

- 理解顾客和其他利益相关方的需求和期望；

- 制定组织的政策和目标;
- 确定实现这些目标所需的过程和职责;
- 确定并提供实现这些目标所需的基础设施和资源
- 建立并应用确定每个过程的效率和效果的方法;
- 识别组织层面和个人层面的潜在利益冲突及其识别和处理方法;
- 确定预防不符合、消除其发生原因的方法;
- 建立和实施持续改进上述过程的过程。

注：虽然本文件针对认证机构审核员，但相关内容（经适当修改后）也可供考虑认可机构评审员公正性问题时参考。

日期：2005 年 7 月 30 日

ISO 9001 审核实践组指南

对内部审核有效性的审核

1. 引言

为使质量管理体系适宜、充分和有效，组织需要进行内部审核以确保 QMS 发挥预期的作用，而且内部审核能够识别体系的薄弱环节和潜在的改进机会。内部审核是对最高管理者的反馈机制；它能够就体系是否符合 ISO 9001：2000 的要求为最高管理者和其他利益相关方提供保证。如何管理内部审核过程，是确保质量管理体系有效性的关键因素。

2. 要求和指南

2.1 ISO 9001:2000 条款 8.2.2 规定如下:

“8.2.2 内部审核”

“考虑拟审核的过程和区域的状况和重要性以及以往审核的结果，组织应对审核方案进行策划。”

这条要求的意图是使内部审核方案关注那些以往曾经发生过问题，或发生的问题可能仍然存在，以及（或）有可能发生问题（因过程本身的性质）的过程和区域。这些问题可能因人为因素、过程能力、测量灵敏度、客户要求变更、工作环境变化等而产生。

内部审核方案应当优先考虑产生缺陷或不符合的风险较大的过程。

如果过程会因诸如下列的因素引发高风险，则应当受到特别关注:

- 过程能力失效的严重后果;
- 顾客不满意;
- 不符合产品（或过程）的法律法规要求。

2.2 ISO 9004:2000 条款 8.2.1.3

“最高管理者应当确保建立有效和高效的内部审核过程，以评价质量管理体系的强项和弱项。内部审核过程可作为独立评定任何指定过程或活动的管理方面的工具。由于内部审核是评价组织的有效性和效率，因此内部审核过程可作为独立的工具，用于获取现有的要求得到满足的客观证据。”

这条指南强调进行内部审核时需要有效地利用资源。

（注：ISO 9004 指南不是 ISO 9001 审核所依据的要求）

3. 审核指南

第三方审核员检查内部审核过程时，应当评价下列方面：

- 内部审核需要的能力及其在内审中的应用；
- 组织在策划内部审核时进行的风险分析（如果有）；
- 管理者参与内审过程的程度；
- ISO 19011 提供的指南（但要注意 ISO 9001:2000 并不要求组织使用 ISO 19011）；
- 组织使用内审结果评价其 QMS 有效性并识别改进机会的方式。

第三方审核员需要：

a) 评价组织识别关键区域和其他参数的方法；

例如，组织是否已识别：

- ■ 影响产品质量的关键过程；
- ■ 复杂过程或需要特别注意的过程；
- ■ 需要确认的过程；
- ■ 需要对人员资格进行评定的过程；
- ■ 需要密切监视过程参数的过程；
- ■ 经常需要校准和/或检定的监视和测量活动，
- ■ 跨多个场所和/或劳动密集型的活动和过程；
- ■ 曾经发生过问题或存在风险的过程；

■ 已确定的对有效性和效率的测量标准做出定义的过程绩效指标，以及这些测量标准是否和组织的总体目标保持一致?

组织在确定对这些过程和活动的审核频次时是否使用了上述信息?

b) 评价组织的内部审核员和审核组的能力;

应当有证据表明组织:

■ 确定了对内审员的能力要求;

■ 提供了适宜的培训;

■ 有内部审核员和审核组表现的监视过程;

■ 审核组包括了有适宜专业知识的人员（这样他们就能够识别出特定过程或活动的偏差可能导致产品质量产生严重后果的情况）。

如果审核员发现下列问题，还应当评价内审员是否理解内审过程结果可靠性的内在风险:

■ 未能考虑对审核结果有实质影响的问题;

■ 选择不正确的抽样方案;

■ 不正确地评价所收集的证据;

■ 偏离审核计划和内部审核程序。

c) 评价审核策划。

组织在实施内部审核活动中，应当能够最大程度地利用可用资源。根据风险来策划内部审核，可以促进资源的有效利用。

审核员应当确定组织（在整个内部审核过程中）是否根据风险来制定内部审核计划，以确保有效和高效地利用资源。这种基于风险的方式还将确保最大程度地降低审核过程失效的内在风险和审核结果的内在风险。

组织应当建立过程，以便在策划以后的内审时利用以前审核的结果。

d) 寻找组织有效实施内部审核方案的证据。

通过考虑上述因素，并检查内部审核过程是否使 QMS 切实得到了改进，第三方审核员应当能够判断组织是否有效实施了内部审核方案，以及内部审核结果是否为 QMS 有效性分析提供了证据。

日期：2005 年 8 月 25 日

ISO 9001 审核实践组指南

对电子化管理体系（EBMS）的审核

1. 介绍

组织在管理体系运行和控制方面对电子介质的依赖性不断增强，这就要求认证机构及其审核员考虑新的方法，以确保审核的有效和高效。他们需要重新确定对过程及相关文件（包括记录）进行评价的方式，以验证其是否符合审核准则。

本文件为审核完全电子化的管理体系，或文件在很大程度上电子化的管理体系提供了基本指南。本文件还针对应在审核前进行的通常的策划和准备活动，为认证机构和审核员提供了补充性指南。

本文件关注 ISO 9001 中那些有可能使用电子文件、记录等的要求，同时还考虑了可能通过电子系统控制上述文件/记录的获取途径的情况。

本文件拟供那些在电子化管理体系（electronic-based management system，EBMS）方面具有丰富实践经验的审核员使用，EBMS 是指依靠电子文件、数据和应用软件来正常运行的管理体系。不过，本文件的写作风格使那些在计算机和 EBMS 方面经验有限的审核员也可以使用本文件。

不论是实施审核的第三方认证机构、实施评审的认可机构，还是实施内部审核的职能部门（以下统称为“审核组织”），审核组织都有责任确保 EBMS 审核过程的有效性。本文采用了 ISO 19011 提供的指南，并对 ISO 9001 和其他管理体系标准的审核员可以用来验证标准符合性的方法提出了建议。为确保使用适当的方法，审核员和审核组织在实施 ISO 19011 所述的审核过程步骤时应当进行必要的调整。

应当注意，认证机构不应当将审核员能够熟练审核 EBMS 作为减少审核时间的理由，而是将其作为优化审核有效性和效率的一种手段。

本文件无意对审核 EBMS 的信息安全控制提供指南。对信息安全控制有兴趣的读者，可以参考 ISO/IEC 17799，该标准是针对信息安全控制的综合性标准。

2. 审核的启动和策划

在审核启动阶段（第一阶段审核），审核组织应当确定受审核组织的结构及其管理体系电子化的程度。对于建立集中的 EBMS 的多场所组织或者“虚拟”组织，需要采用与单一场所和（或）有形组织不同的审核计划和方法。

审核组织和受审核方应当商定审核员将如何访问和使用 EBMS。这可能需要考虑以下方面:

— 允许审核组成员有机会熟悉受审核方的 EBMS(包括在审核计划里为此安排充足的时间）;

— 受审核方信息技术设施的使用政策;

— 访问指导书、必要的访问安全许可、相关的组织文件和记录;

— 确保审核员在审核中和审核后对电子文件和记录予以保密的保障措施和过程。

审核组织应当确保所挑选的审核组有足够能力对 EBMS 进行有效的审核。

3. 文件审查

取决于受审核方能否通过电子邮件传输文件，或使审核员通过网络获取文件，审核组织可以在现场以外，通过在线方式或电子邮件提交的电子文件，进行部分或全部的文件审查。

出于技术和安全原因，审核组可能不能在到达现场前，通过在线方式或电子邮件传送的相关文件对组织的 EBMS 进行完整的文件审查。这种情况下，审核组需要在第一阶段审核中，在受审核方的设施对电子文件进行审查，以满足审核准备活动的要求。

4. 现场审核活动的实施

EBMS 的审核方法很大程度上取决于在判定符合性时，需要多少电子记录形式的证据。

现场审核活动中，审核路线通常应当包括受审核过程的物理场所。但是，对于 EBMS，审核员可能需要在计算机工作站上花费大部分时间对证据进行确认，以确定是否符合要求，而计算机工作站的位置可能不一定位于实际过程附近。

如果计算机工作站位置较远，不能从实际过程的地点访问，那么可以减少在实际过程的地点实际使用的审核时间。但是，由于可能要在确认实际过程存在之前或之后对电子证据进行审查，总的审核时间可能不一定需要减少。

当相关的计算机工作站位置较远时，应当特别考虑在实际过程的地点和计算机工作站之间往返所需的时间。

如果过程需要人员介入，审核员应当对实际过程与电子介质之间发生相互作用的方法进行评价，以确保相关信息的准确性。

5. 审核电子文件的控制

规定管理体系方针和程序的电子文件可以采用多种文件格式，这取决于组织使用哪种应用软件生成这些文件。电子文件格式包括文本文件、HTML 文件、PDF 文件等等。电子数据表和数据库也被认为是附属于管理体系控制要素的电子“文件”。

由于现在使用者可以相对容易地生成电子数据表和其他电子文件，审核员应当确保受审核方通过适当的程序，将通用的管理体系文件控制政策用于电子文件。

在电子化环境中，组织需要采用适宜和有效的方法来确保管理体系文件的充分审查、批准、发布和分发。这些方法应当与电子文件的编制和修改方法保持一致。

在很多情况下，文件控制措施还可能是生成文件的应用软件中的标准功能。因此审核员应当对这些应用软件中的特定控制有一定程度的了解，以便基于这些控制来判定是否符合适用的管理体系标准。

由于 EBMS 提高了对文件进行修改、更新、格式变更和其他改进的能力，审核员应当特别关注像文件标识和文件修订级别这样的控制要素。

由于电子介质便于对文件进行修改，审核员应当验证组织的文件控制政策和程序是否考虑了用于管理过期文件的控制措施。

审核员应当验证 EBMS 文件在电子文件的功能和控制方面为使用者提供了指导。另外，组织在文件访问政策中部分地反映适用的管理体系标准关于“在使用处可获得适用文件的有关版本”的要求，是一种有代表性的做法。审核员应当理解组织关于用户权限的政策和程序，因为这些是正确实现组织的过程的重要因素。

通过电子方式与供方、顾客及其他利益相关方进行的外部沟通可能涉及文件交换。由于外部文件可能规定组织过程运行的关键参数，审核员应当验证 EBMS 正式导入和控制这些文件的程度。

6. 审核电子记录的控制

电子记录由过程输出的数据和存储这些数据的电子格式组成。这些电子格式包括从简单的电子数据表到更为复杂的数据库应用软件。

审核员应当意识到，组织对电子表格的控制要素不一定与电子记录的控制要素相同。例如，对于电子表格和电子记录的标识，一份电子表格的标识对应的是这份电子表格的专用名称，而电子记录的标识则要同时针对存储在一份电子表格中的一组特定数据和这份电子表格。

审核员应当审查组织采集数据的方法，以确保数据录入活动的准确性有足够的可信度。

在评价组织对记录存储的控制时，审核员应当验证组织是否了解其存储容量和下列因素:

— 生成记录的速度;

— 记录保留的政策和相关的保存期限;

— 清楚记录的速度。

这些因素可能影响 EMBS 的正常运行。

由于组织的知识库和绩效信息可能几乎全部保存在电子记录中，审核员应当审查组织的电子信息安全防护方法。ISO/IEC 17799 提供了更多关于信息安全的资料。

7. 组织的资源

随着越来越多的组织使用 EBMS，IT 部门的作用越来越重要。审核员应当验证组织是否配备了与确保 EBMS 持续有效运行相适应的 IT 资源(包括设施）。

审核员还应当验证组织是否规定了 IT 人员参与 EBMS 建立、实施、维护和文件管理相关事务的程度，和对这些方面施加影响和提供支持的程度。

在验证资源配置是否适当时，审核员应当评价组织如何解决 EBMS 运行所需硬件和软件的操作人员的能力问题。

在建立 EBMS 时，组织通常让原有体系和电子化体系平行运转一段时间，以便使用者适应电子化体系。遇到这种情况时，审核员应当验证组织为确保其人员确实学习和掌握 EBMS 而采用的方法。

组织的 IT 设施复杂程度各不相同，取决于业务的性质和复杂程度。审核员应当验证组织对 IT 平台的系统维护政策和程序。审核员还应当验证组织如何应对系统故障停机事故，因为这些将影响 EBMS 的正常运行。审核员应当验证组织是否有正式的备份系统，以及是否定期检查和测试备份系统的充分性和有效性。

在软件方面，审核员应当验证组织对内部软件、外部软件、软件许可以及软件升级的控制。由于软件可以被看作一种动态的电子文件，所以上文关于文件审核的指南也适用于软件。

根据组织 EBMS 使用软件的程度，审核员应当审查应用软件的功能以及软件和标准规定的管理体系要素之间的关系。

由于环境因素可影响 IT 平台的运行，组织应当采取措施避免平台受到环境因素的影响。这些措施可能包括从提供足够的设施或保护箱、罩，到提供不间断电源（UPS）。审核员应当评价组织的控制是否考虑了像设施维护、温度、湿度等等这样的因素对 EBMS 运行的影响程度。

8. 内部和外部的电子化沟通

电子化沟通的方便程度不断提高，可供选择的方法也越来越多，因此组织的文件化管理体系应当对电子化沟通的方法做出必要的规定，以确保使用这些方法时的一致性，从而满足 EBMS 和适用的管理体系标准的要求。

当组织通过局域网、电子邮件和实时通讯来满足 EBMS 的要求时，审核员应当验证组织的政策和程序是否规定了这些方法的使用条件。另外，

如果将内部电子化沟通的结果作为满足审核准则的证据，审核员应当验证是否遵循了记录控制政策和程序。

当组织依靠 IT 设施与顾客（例如电子商务）、供应商（电子采购）、外部场所和其他相关方进行电子化沟通时，审核员应当验证 EBMS 是否正式规定了这些沟通和相关交易的方法、政策和程序。

9. 多场所管理体系

采用多场所（或者从一个中心场所到卫星场所）运营方式的组织通常通过电子化手段与其不同场所保持沟通，共享政策、程序和过程数据，例如通过互联网、外部网络、电子邮件和实时通讯。

如果组织通过 IT 平台和关联的应用软件共享与审核准则相关的信息，那么审核员应当对组织使用的不同网络手段有一定程度的了解，以便判断 EBMS 是否符合审核准则。

审核员应当验证组织的政策和程序对多场所管理体系的控制做出了适当的规定。

10. 审核员能力

随着组织越来越多地依靠软件来对运作进行监视和控制，EBMS 审核过程的可信性将取决于审核员理解信息技术发展趋势的能力。

审核组织应当通过必要的措施（包括提供培训）满足审核员对下列方面的知识和技能的一般和特殊需求:

— 可能影响管理体系运行的信息技术普遍发展趋势;

— 与每项审核任务特定相关的方面。

由于 IT 领域的创新与审核准则的变化相比较为迅速，审核员和审核组织面临的一项挑战是需要切实了解相关的趋势及其在 EBMS 中的应用。

对于影响 EBMS 运行的创新，审核组织应当确定审核组自身是否具有进行有效审核所需的经验，或者是否需要技术专家的协助。

对资源管理的审核

审核员应当验证受审核方对实施、保持和改进质量管理体系所需的资源进行了充分、适宜的管理。这意味着组织要识别适当的资源，并规划、提供、使用和监视这些资源，必要时还要对这些资源进行变更。

我们建议审核员不要孤立地对资源管理进行审核。不管组织的结构如何以及怎样确定其过程，审核员都应当能够验证组织的资源管理在实现其所策划结果方面的充分性、适宜性和有效性。对审核员来说，重要的是验证组织在决定配置哪些资源时，是否对过去和现在的绩效进行了评价（例如，使用成本—效益分析、风险评估）。

审核员可以通过与最高管理层和其他责任人进行面谈来检查受审核方是否建立了适宜的过程，从而对资源的管理做出评价。但是，这种方式需要得到审核中收集的客观证据的支持。

审核员可以在审核的不同阶段收集证据，例如对输入、过程绩效和输出进行评审。在对所有的过程及相关的体系和过程文件进行审核时，都必须收集证据，例如:

- 管理承诺和职责;
- 管理评审过程;
- 产品实现过程，包括不合格品的控制，纠正、预防措施和持续改进。

审核员应当避免对组织资源配置的充分性和适宜性做出主观的判断，而应当仅限于对资源管理过程的有效性进行评价。

审核员应当验证人力资源、基础设施（电力、供水设施、设备维护、通信、信息技术等）、工作环境（温度、照明、振动、噪声等）的提供和保持方式是否与质量方针和目标相一致，有利于产品符合要求。

如果发现组织没有考虑对资源进行有效的管理，可能导致产品不能满足要求，这应当作为不符合处理，不符合的程度应当取决于相关的风险。

日期：2005 年 12 月 12 日

ISO 9001审核实践组指南

审核“顾客沟通”

1. 介绍

有效的顾客沟通有助于质量管理体系和组织最终取得成功。相反，组织与顾客之间的许多问题都可以追溯到缺乏沟通和交流。

2. 要求和指南

2.1 ISO 9001:2000条款7.2.3规定:

“顾客沟通”

组织应对以下有关方面确定并实施与顾客沟通的有效安排:

a) 产品信息;

b) 问询、合同或订单的处理，包括对其修改;

c) 顾客反馈，包括顾客抱怨。

2.2 APG已发布了一份关于对顾客反馈过程进行审核的指南。

2.3 ISO 9001:2000关于顾客沟通的其他要求:

在ISO 9001:2000中还有一些对顾客沟通的直接或间接要求:

- 最高管理者应以增强顾客满意为目的，确保顾客的要求得到确定并予以满足;（条款5.2）
- 组织应评审与产品有关的要求。评审应在组织向顾客作出提供产品的承诺之前进行(如: 提交投标书、接受合同或订单，以及接受合同或订单的更改）;（条款7.2.2）
- 如果顾客提供的要求没有形成文件，组织在接受顾客要求前应对顾客要求进行确认（条款7.2.2）; 组织需要有一套获得这些要求的系统。

- 经有关授权人员批准，适用时经顾客批准，让步使用、放行或接收不合格品。（条款8.3b）

2.4 ISO 9004:2000中的指南（条款7.2）

“与利益相关方有关的过程

管理者应确保组织对与其顾客和其他利益相关方相互认可的有效和高效的沟通过程作出规定。组织应实施和保持这样的过程，以确保充分理解相关方的需求和期望，并将其转化为组织的要求。”

3. 验证顾客沟通的有效性

验证顾客沟通有效性是达到顾客满意的关键环节。尽管ISO 9001:2000没有根据组织的规模、复杂度及企业文化对文件化程序提出特殊的要求，但为了保证顾客沟通过程的有效实施，还是需要有一个文件化的程序。

ISO 9000中定义“顾客”为产品的接受者，并且进一步给出了顾客（包括最终用户）的实例。

许多组织通过经销商和零售商出售他们的产品或提供服务，而不是直接接受最终用户的订单。对于审核员来说，重要的是验证组织是怎样就产品或服务的质量与最终用户进行沟通的，以及组织从最终用户获得反馈（包括抱怨）的机制。审核员应当认识到有些时候经销商和零售商的需求和最终用户的需求是不同的。

4.审核的方法

4.1 与顾客的沟通通常为三大类:

- 组织与现有或潜在的顾客的一般性沟通，例如：广告或市场信息;
- 与顾客问询、要求或订单相关的特定沟通;
- 为回应顾客反馈和抱怨而进行的沟通。

4.2 审核员应当注意观察组织与顾客进行一般性沟通的以下方式:

产品信息，包括:

- 广告材料
- 网站
- 产品目录单

若组织接受经销商而不是最终用户的订单，审核员应当确定最终用户是否全面、准确地得到了有关产品或服务的描述信息（用户手册、说明书、网站等）。审核员还应当确定顾客需求是如何被识别以及产品要求是如何满足的。

4.3 审核员应当验证产品信息，以确保顾客或潜在顾客很容易得到这些产品信息，且提供的信息是及时的，准确的。例如，审核员可以询问组织按照什么频次对广告材料、网站和产品目录单进行审查以确保其反映当前产品的提供和服务情况；若个别产品修改、中止或不再有效，组织相应采取了哪些措施。

4.4 审核员应当注意观察组织与顾客进行的下列特定沟通:

问询、合同或订单的处理，包括对其修改:

- 报价
- 订单格式
- 订单的确认
- 订单的修改
- 文件的递交
- 发货单
- 信用证
- 电子邮件和普通信函
- 来访记录或来自/发送给顾客的信件

顾客反馈和抱怨的管理过程

- 抱怨信件
- 回执

4.5 审核员还将在许多地方对组织和顾客的沟通进行检查，如:

- 在订货过程中，如顾客提供的要求没有形成文件，组织需要建立一套系统，以便在接受顾客订单前获得或确认顾客的这些要求;
- 在设计、开发过程中，组织应当与顾客保持适当的沟通;
- 让步使用、放行或接收不合格品的过程中，需要有关授权人员批准，适用时要经顾客批准。

4.6 审核员可以使用常用的追溯方式来验证组织是否符合ISO 9001有关顾客沟通的要求，以及组织在问询、合同或订单处理的过程中与顾客沟通的有效性。

日期：2006 年 12 月 8 日

ISO 9001 审核实践组指南

对设计和开发过程的审核

1. 介绍

对设计和开发过程进行审核的目的是确定组织对设计和开发过程的管理能够使产品满足预期的使用目的和规定要求。

需要注意的是，对于服务业组织，进行设计和开发的方法可能与“传统”的制造业组织不同（参见《对服务型组织的审核》）。

在深入讨论应当采取什么方式来对设计和开发过程进行审核之前，重要的一点是审核员要理解“设计和开发”这个短语的含义。许多组织因为错误理解这一概念，因而错误地在他们的质量管理体系中删减了该过程。

ISO 9001:2000 条款 7.3 只提到**产品和服务**的设计和开发。在一些组织中，对**过程**的设计和开发采用相同的方法可以带来好处，但这并不是标准的要求。

产品设计和开发是将产品要求（例如规范、法规要求和具体的或隐含的顾客要求）转化为规定的产品特性（“产品的区别性特征”）的一组过程。ISO 9000:2005 条款 3.4.1 对产品特性举例如下:

- 物质特性（例如机械、电、化学或生物特性）;
- 感观特性（例如与嗅觉、触觉、味觉、视觉和听觉有关的特性）;
- 行为特性（例如礼貌、诚实、准确）;
- 时间特性（例如准时、可靠、可用）;
- 工效学特性（例如生理特性，或与人身安全有关的特性）;
- 功能特性（例如一架飞机的最大速度）。

为了确定组织是否事实上有设计和开发，审核员需要确定谁负责定义产品或服务的特性，以及如何和在何时进行确定。

（注：这可以适用于原始设计或之后的设计变更）

通常，设计和开发过程包含图 1 所示的阶段。每个阶段都有特定的产出，这些产出均覆盖了产品设计与开发的商业和技术方面。在一些情况下，组织可能能够有合理的理由从其 QMS 中删减标准的某些分条款（sub-clause）或个别要求，但不必删减整个条款（clause）。如果组织的产品设计已经完成了很长时间，并且经过了良好的确认，组织可能需要确保根据条款 7.3 对设计变更进行管理。审核员应当验证删减的合理性。

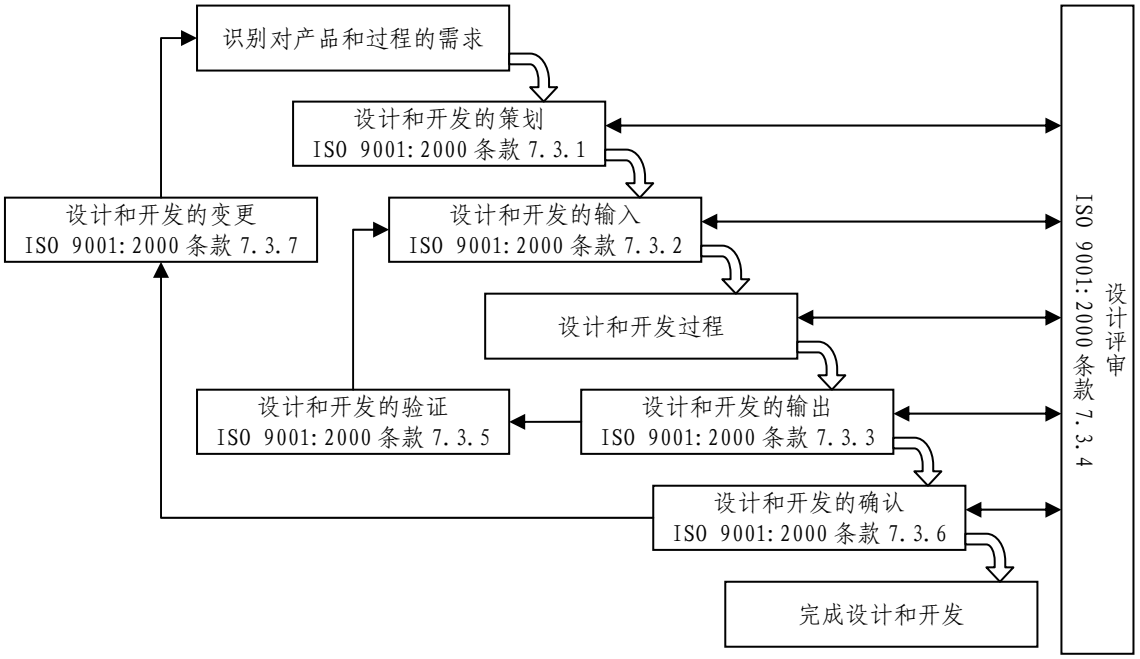


图 1 – 设计和开发过程概览

审核员应当确定组织已实施了、正在实施哪些设计和开发项目。审核员应当选取足够数量的项目，以便能够审核到设计过程的各个阶段。

下面给出了审核设计和开发过程各个阶段的指南。但是应当注意，审核员有可能无法从选取的所有项目中审核到所有阶段。

2. 对设计和开发需求的审核

设计和开发需求的来源包括:

- 组织的战略策划;
- 市场情报和研究;
- 服务报告;
- 顾客反馈和需求;
- 新的或更新的法规要求;
- 过程的变化;
- 新技术;
- 供方。

审核员应当评价组织是否有审查上述需求的机制和活动。尽管这不是标准的要求，但这样有助于审查组织是怎样做出进行设计和开发的决定的，即是否考虑了风险和成本因素，是否征求了所有相关的职能部门（内部或外部的）的意见。

3. 对设计和开发策划的审核

对策划职能进行审核时，应当考虑下列问题:

- 设计策划过程的总流程是什么样的?
- 设计策划过程是怎样描述的?
- 需要什么样的资源和能力?
- 设计工作的哪个部分将被外包?
- 谁负责? 明确了权限吗?
- 怎样来识别和管理不同群组之间的接口（内部的或外部的）?
- 是否确定了需要进行验证、确认和评审的节点?
- 是否确定了主要的里程碑和时间表?
- 是否对计划的实施和有效性进行了监视?
- 是否将计划向所有相关的职能部门做了必要的传达和更新?

4. 对设计和开发输入的审核

在审核设计和开发输入时，审核员应当去理解组织是怎样根据下列方面来识别自己的输入的:

- 组织的产品和过程;
- 财务、经济、健康和安全问题;
- 组织的风险和影响;
- 顾客的要求和期望;
- 适用于产品的法律法规要求。

审核员应当评估在没有考虑到相关输入时的风险、对顾客满意度的影响和组织可能遇到的问题。

5. 对设计和开发评审的审核

审核员应当验证组织按照原始计划对设计和开发的总体过程进行了控制，并定期对该计划进行审查，还应当验证组织在所策划的适当阶段进行了验证设计和开发评审。

审核员在检查评审过程时，应当考虑下列问题:

- 在设计过程中，是否在所策划的阶段进行了评审?
- 是否以系统的方式进行了评审，与接受评审的阶段有关的职能部门的代表是否参加了评审?
- 是否考虑了所有原有的输入和任何新输入?
- 原来的输出是否依然合适，或者修改后的输出是否得到了标识?
- 输入和输出在被修改后，是否经过了评审，并由具有相关职责和权限的人（适用时，包括顾客）批准?
- 输出是否证实所设计的产品是适宜、充分和有效的?
- 是否达到了相关的设计目标?
- 评审是否留下了足够的记录?

6. 对设计和开发输出的审核

设计和开发的输出应当符合组织所识别的需求，以确保所得到的产品能够满足预期的使用。输出可以包括与下列相关的信息:

- 营销、销售和采购;
- 生产;
- 质量保证;
- 产品交付后的服务提供和维护信息。

而且设计和开发输出的形式应当使验证和确认活动能够得以实施。

审核员应当从所选取的项目中获得证据，以确认:

- 可以获得关于设计和开发各个阶段的完成情况的信息;
- 对于所评审的阶段，设计和开发过程已经完成;
- 设计和开发输出已经过确认。

7. 对设计和开发验证的审核

设计和开发验证的目的是确保设计和开发活动的输出已经满足了该活动的输入要求，如下面图2所示。

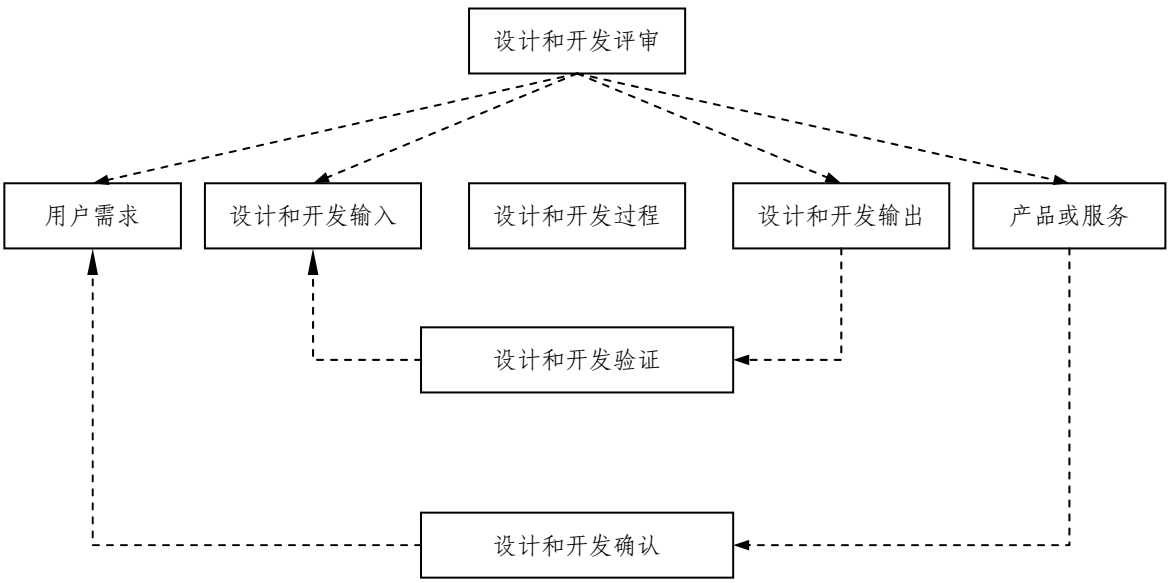


图 2

设计验证可以包括诸如下列的活动:

- 用另一种方法进行计算（验算）;
- 将新的设计规范与一个相似的经过证明的设计规范做比较;
- 进行证实，包括制作原型（模型）、进行模拟或检测;
- 在文件发布前对其进行审查。

审核员应当确定设计和开发验证活动能够使人相信:

- 对所需的验证进行了策划，并在设计和开发过程中进行了适当的验证;
- 所完成的设计或开发是可以接受的，结果与最初的要求一致，并能够追溯到最初的要求;
- 所完成的设计或开发是一系列事件、输入、输出、接口、逻辑流程、时间分配等以正确的方式共同作用的结果;
- 设计或开发提供了保险性、安全性以及与其他要求和设计输入的符合性;
- 有证据表明验证结果和任何进一步的行动已得到记录，并在行动完成时得到了确认。

审核员应当确定只有经过验证的设计和开发输出才被提供给下一阶段。

8. 对设计和开发确认的审核

设计和开发确认是通过检查和提供证据来确认预期使用方面的具体要求得到了满足。换句话说，确认过程是否能够检查出最终的产品和(或)服务将满足，并确实满足顾客的使用需要?

作为设计和开发策划过程的一部分，应当对确认方法做出规定，不过在设计和开发的实施中仍可以对此进行修改。

对于许多产品和（或）服务，确认是一个相对简单的过程。例如，对于一个办公室家具的新设计，可以通过对原型进行检测，然后对完成后的产品的最初样品进行检测，来进行确认。

然而，在其他很多情况下，设计确认将更复杂。例如，用于电子或电气系统中的产品或部件可能必须符合多项由其他系统设计公司制定的性能要求。在这种情况下，只有从这些系统设计公司，或者从产品或部件的使用者那里获得性能的信息（最好是正式的检测结果），才能完成设计确认。

另一个有难度的例子是由客户或其他外部组织来进行设计确认（例如对建筑和工程设计的确认）。

在上述的复杂情况下，组织需要就如何进行设计确认，以及如何沟通和共享确认结果，来寻求与相关的外部方达成一致。此时，组织的设计和开发策划中要对设计确认的实施和完成做相应的规定。

审核员应当确保:

- 有记录证明已进行了确认;
- 确认是按照所策划的确认安排进行的;
- 确认表明所得到的产品能够满足规范的要求;
- 在实际可行时，在交付或实施前已进行了确认;
- 对为纠正与设计和开发输入的不符合而采取的必要措施以及不符合的原因做了记录。

如果不能在产品的交付或实施前进行确认，那么审核员应当确保组织在尽可能早的时候进行了确认，例如在对一个复杂的设施或工厂进行试运行时。审核员还应当确保组织已告知客户确认不能提前进行。审核员应当确定只有经过确认的设计和开发输出才被提供给客户使用。

9. 对设计和开发变更的审核

组织需要对设计过程中的设计和开发变更进行控制。审核员应当考虑以下方面:

- 变更的来源和请求是否得到了正确地识别和沟通?
- 对变更的影响进行评估了吗?
- 在适当时，是否追加了设计证明或设计测试?
- 是否评估了变更对已经交付的部件和产品的作用?
- 在实施变更前，是否经过了适当的批准（这可以包括行政审批或客户的批准）?
- 是否对变更做了完整的记录，记录是否包括任何必要的附加措施的信息?

日期：2006 年 12 月 8 日

ISO 9001 审核实践组指南

审核中的文化因素

介绍

审核员在职业生涯当中，可能需要审核许多内部文化以及所处的民族文化、社会文化、经济文化、政治文化或宗教文化迥异的组织。

对于审核员来说，重要的是敏锐地把握这些文化问题，以避免可能的冲突，同时在审核中保持公正，并实现审核目标。

审核员还需要用使人能够理解的方式来表达自己，特别是在涉及到语言问题时。应当记住，审核员有责任根据受审核方的语言技能来调整自己的方式方法，审核结论不应当因为受审核方在语言表达能力方面存在欠缺而带有成见，这一点很重要。还有，一个组织的不同部分可能存在不同的文化和语言因素，例如跨国公司。

指南

在审核的所有阶段都需要考虑文化因素。

1）审核策划

a. 审核中开始考虑文化因素的最佳时机是在策划阶段，这可以包括:

   i. 审核组的选择（考虑个人特点，包括性别、语言能力、社交能力、可能的文化冲突）;

   ii. 审核日程安排（尽可能考虑典型的工作时间、传统、假期、就餐时间、祈祷时间等）;

   iii. 考虑是否需要独立的翻译并为此安排额外的时间;

   iv. 使审核组认识到可能存在敏感的文化问题的任何方面。

b. 尽可能使用熟悉当地语言和习惯的审核员是一种好的做法。在审核

前寻求指导可能也是另一种适宜的做法。

c. 应当在第一阶段审核中对任何重要的文化因素进行评价，而且在第二阶段以及后续审核之前对策划进行修改可能是适宜的。

2） 组织的内部文化

所有组织都不相同，没有“标准的”内部文化。内部文化可能会独立于组织所处的外部文化。这里面有许多因素需要考虑。下面是一些例子。

a）礼仪和着装要求的程度

如果审核员的着装过于不正式，可能会在心理上处于劣势，为此多数认证机构规定了相应的着装要求。但同样重要却经常被忽视的一点是，如果审核员穿着过于讲究或正式，又可能使审核员感觉不舒服，或让受审核方感到拘束并影响审核结果。我们对审核策划的一点有用的建议是，让审核员的穿着像受审核组织的管理人员。审核一个热带国家的农场，与在寒冷天气下审核一个重要金融中心的投资银行，着装要求当然会有很大差别。预访问、第一阶段审核和基本常识是帮助确定哪种着装比较适宜的有用工具。

b）组织的等级层次

审核员要认识到***正式***不一定意味着***好***，而***不正式***不一定意味着***不好***，这很重要。一些经营得很好的组织在管理风格上很不正式，特别是在不同等级层次之间的互动和交流方面。

审核员需要对组织的等级层次保持敏锐，但不应当怯于直接与从事实际工作的人员进行交流。审核员应当全力避免“仅和管理层交谈”的倾向，但可以多给管理层一点面对面交流的时间，以免使他们觉得尴尬。

c）处理负面审核发现的方法

以正确的方式开出审核中发现的所有不符合适并呈递给组织是十分重要的（参见 APG 关于开具不符合项的指南）。一些组织的文化对不符合非常敏感和排斥，在一些情况下管理层可能会试图怪罪“责任人”。这将增加审核中的紧张气氛，但不应当阻止审核员开出这些不符合。不过，审核员强调审核的目的是对体系而不是个人进行验证，可能是适宜的做法。审核员应当在首次会议时就指出这一点。

3）外部（当地或地区的）文化

要对审核员可能需要面对的所有文化状况给出指南是不现实的，但一些基本指南总是有用的。审核员可能需要注意的因素包括，例如:

- 语言
- 饮食习惯
- 社会等级差别
- 性别问题的敏感程度
- 着装风格
- 肢体语言
- 自尊和民族自豪感（特别是对待不符合的态度）
- 宗教信仰和重要的宗教节日或假期
- 当地习俗
- 敏感的政治问题

通常，审核员的黄金法则是从不参与宗教或政治讨论，但在审核前认识到这些问题和其他潜在的文化因素可以有助于避免以后的尴尬或冲突。

审核员应当总是努力适应当地文化，但这样做时，应当确保不会影响审核的客观性和结论。

日期：2006 年 12 月 8 日

ISO 9001 审核实践组指南

“重要的是结果!”

1. 介绍

针对不断增加的对获证组织没有交付一致的、符合顾客要求的产品的关注(参见 ISO 9001:2000 条款 1.1),ISO 9000 顾问组(由 ISO/TC 176, ISO/CASCO, ISO/COPOLCO, IPC 和 IAF 的代表组成)最近提出了一系列建议。

下文由杰克·维斯特撰写，最初刊登在 2006 年 7 月出版的《质量文摘》杂志。这片文章对上述问题进行了论述，并强调了“重要的是结果!”这一主题思想。

符合 ISO 9001:2000 的单个要求是重要的，例如文件控制、记录控制、人员能力、测量设备的校准，但不应当是质量管理体系的中心关注点。应当把满足这些要求看作实现所期望的结果的手段，这个结果就是一致的、合格的产品。

2. 杰克·维斯特的文章

人们常说一个组织可以有符合ISO 9001的很好的质量管理体系，然而仍生产“垃圾”。这种观点产生于第三方QMS认证和产品认证之间所存在的很大的但又是合理的区别。对QMS进行认证并不是绝对保证获证组织生产的产品将符合要求。然而，把ISO 9001中的许多要求结合在一起，应当为体系的输出符合顾客要求提供合理的保证。

ISO 9001要求组织的质量方针包含对符合要求和持续改进QMS的承诺。标准要求对产品设计进行确认以确保它们符合特定的使用要求。ISO 9001还要求对产品进行验证以确保其符合要求。识别和满足顾客要求是

始终贯穿ISO 9001的主题。例如，管理评审的期望输出之一就是对不满足顾客要求的产品做出决定。

ISO 9001中证明“重要的是结果”的条款	
1.1 范围	本标准为有下列需求的组织规定了质量管理体系要求: a)需要证实其有能力稳定地提供满足顾客和适用的法律法规要求的产品; b)通过体系的有效应用，包括体系持续改进的过程以及保证符合顾客与适用的法律法规要求，旨在增强顾客满意。
5.2 以顾客为关注焦点	最高管理者应以增强顾客满意为目的，确保顾客的要求得到确定并予以满足(见7.2.1和8.2.1)。
5.3 质量方针	最高管理者应确保质量方针: …… b)包括对满足要求和持续改进质量管理体系有效性的承诺;
5.6.3 评审输出	管理评审的输出应包括与以下方面有关的任何决定和措施: …… b)与顾客要求有关的产品的改进;
6.1资源提供	组织应确定并提供以下方面所需的资源: …… b)通过满足顾客要求，增强顾客满意。
7.2.1与产品有关的要求的确定	组织应确定: a)顾客规定的要求，包括对交付及交付后活动的要求; b)顾客虽然没有明示，但规定的用途或已知的预期用途所必需的要求; c)与产品有关的法律法规要求; d)组织确定的任何附加要求。
7.3.2 设计和开发输入	应确定与产品要求有关的输入，并保持记录(见 4.2.4)。这些输入应包括: a)功能和性能要求;
7.3.6 设计和开发确认	为确保产品能够满足规定的使用要求或已知的预期用途的要求，应依据所策划的安排 (见7.3.1)对设计和开发进行确认。
8.2.1 顾客满意	作为对质量管理体系业绩的一种测量，组织应对顾客有关组织是否已满足其要求的感受的信息进行监视，并确定获取和利用这种信息的方法。
8.2.4产品的监视和测量	组织应对产品的特性进行监视和测量，以验证产品要求已得到满足。这种监视和测量应依据所策划的安排(见 7.1)，在产品实现过程的适当阶段进行。

我们需要打破这样的“神话”：组织在实实在在地符合ISO 9001的同时，仍然可以生产出不满足顾客要求的产品。获得ISO 9001认证的组织和审核员都趋向于关注ISO 9001的细节，而经常忽视了最基本的要求。一定不要忽视产品！如果声称一个组织符合ISO 9001，应当对顾客意味着这个组织能够一致地提供符合顾客要求的产品。

我们必须肯定我们的体系向我们的顾客交付合格的产品。标准要求做到这一点，ISO 9001的可信性要求做到这一点。对我们的顾客来说，重要的是我们的QMS输出的结果。

注：这篇文章总结了几个与ISO 9001:2000有关的重要概念，这些概念在《解释ISO 9001:2000》（第2版，Charles A. Cianfrani, Joseph J. Tsiakals and John E. (Jack) West著，ASQ质量出版社2001年出版）中做了详细解释。

关于作者

杰克·维斯特（John E. (Jack) West）是一位咨询师、商业顾问和作家，在许多行业有着超过30年的覆盖多个行业的经验。

日期：2007 年 7 月 2 日

ISO 9001 审核实践组指南

对采购和供应链过程的审核

1. 介绍

许多组织在建立管理体系时，会采用他们认为符合 ISO 9001:2000 条款 7.4 的方式，通过系统对产品采购和采购产品的查验进行控制。相似的，审核员可能认为，只要通过检查批准过的供应商名录是否保持最新，企业是否只从批准过的供应商那里采购，以及是否进行了确保满足规定的采购要求的必要活动，就足以确认。

当在许多情况下，上述做法可能不足以保证采购的产品在各方面都满足最初的规范。这种情况下，对更多有关采购管理的过程和供应链进行检查是更可取的。

2. 审核采购过程

审核采购管理过程时，应当注意:

- 采购是在产品设计和开发中规范编制完成之时开始的;
- 相关部门之间，就确保潜在的供应商能够按照所要求的成本提供满足设计规范的产品进行了讨论;
- 组织应当在与供应商进行沟通前，确保所规定的采购要求是正确的;
- 采购要求当中已经包括了法律法规要求;
- 企业已经评价了部件产品相关风险的程度和为确保它符合设计规范而需要进行的控制。

对上述几点的确认方式的几点实际建议:

- 确认采购订单中的规范与所设计的规范（或从顾客那里得到的规范）是一样的;
- 确定组织在设计过程中，或在订单下达前，是否与潜在供应商就关键部件的设计规范进行了协商;
- 在向供应商确认最终的规范/订单前，规范是否经过了某种形式的批准?
- 采购订单中是否包含或引用了法律或法规要求?

3. 审核供应链

在许多情况下，审核员在审核供应商的选择和评价是，只是简单地检查组织批准过的供应商名录以及组织是否定期审查了这份名录。这种做法在很多情况下并不能充分保证组织对其供应链中所有供应商都进行了有效的控制。需要考虑的问题有:

- 企业在选择关键部件产品的供应商时，是否只考虑他们能否以便宜的价格供货，还是要考虑他们持续地提供符合规范的产品的能力?
- 在批准供应商时，是否仅根据他们有没有通过公认的质量标准认证，或者是否对他们的认证范围进行了审查?

  注: 在一些情况下，企业对有意向的供应商进行第二方审核，以建立清晰的沟通渠道、明确产品规范和交货要求等，对企业来说可能是一种有利的做法。
- 企业起先因质量问题拒绝产品，在供方降价后又接受该产品的频次?
- 企业在接受先前被拒绝的产品时给出了多少让步?

4. 结论

通常，一个有经验的审核员根据常识，自然会去检查组织的采购过程和供应链，但在有些情况下，产品和部件的性质可能表明有必要做进一步的调查。每个产品和所有每次审核面对的情况都是独特的。

Date: 30 July 2005

Accreditation Auditing Practices Group Guidance on:

The Witnessing of CRB Audits by an Accreditation Body

1. Introduction

The witnessing of Certification / Registration Body (CRB) audits on their clients by Accreditation Bodies (ABs) is valuable for:

- verifying, on site, the effectiveness of a CRB's programmes and procedures (and especially with regard to their assignment of competent audit teams).

- observing the CRB's auditors, as they perform a registration/ certification, a re-certification, or a surveillance audit, to evaluate if they:
    - comply with the CRB's procedures,
    - adequately address the recommendations of:
        - ISO/IEC Guide 62,
        - Relevant IAF Guidance
        - ISO 19011:2002,

      and, as applicable, any relevant sector specific requirements.

This will enable an AB to determine whether the CRB is effective in controlling its decision making and certification processes, and thus to assess the CRB's capability to perform accredited certification.

2. Pre-audit preparations

In order to be able to witness audits, an AB will need to have formal arrangements in place with its accredited CRBs, and with those CRBs that are in the process of applying for accreditation. These arrangements should ensure that the AB has the right to witness CRB audits, as it sees necessary, and that the CRBs have arrangements in place with their clients to permit such witnessing to be conducted.

These arrangements may need to address issues such as confidentiality, between the AB and the CRB, and between the AB and the CRB's clients.

When deciding if a CRB needs to have an audit witnessed, the AB should take into account factors such as:

- the CRB's overall performance,
- the risks associated with the industry and service sectors that the CRB operates in,
- feedback from interested parties,
- the results of the CRB's internal audits, etc..

The AB should also ensure that their presence at the audit is cost effective and try to minimise impact on the CRB and its client.

When planning to witness an audit, the AB should ensure that it has relevant information concerning the CRB. This should include, as appropriate, details of:

- the organizational structure of the CRB
- its quality management system,
- its operating procedures,
- the results of previous audits on the CRB,
- complaints brought to the attention of the CRB, and to the AB itself.

Additionally, in relation to witnessing a specific audit (on a specific CRB and a specific client of the CRB), the AB should also ensure that it has details of:

- the CRB's audit plan,
- background information on the CRB's audit team,
- the history of the CRB's client, and the client's quality management system
- Logistical information for the audit (e.g. the date and location of the audit).

An AB should have a formal process for the selection and appointment of its own auditors. An AB should only assign a competent auditor, or auditors, to witness CRB audits. The AB auditor(s) should have:

- an appropriate knowledge of the CRB's client's type of business, processes and products
- a general understanding of the kinds of regulations the client's products have to comply with, and
- the ability to witness an audit and to collect any necessary information.

In advance of witnessing an audit, the AB should inform the CRB of:

- its objectives for witnessing the audit
- its assessment process
- its feedback and reporting processes.

The AB should also agree with the CRB the role that its auditor(s) will play during the audit, and on how this will be presented to the client.

It should be made clear to all interested parties that the AB's auditors, when witnessing the CRBs' audits, are not directly auditing the CRB client's quality management system, as this is the sole duty and responsibility of the CRB.

3. During the audit

During their witnessing of CRB audits, AB auditors should limit their participation in the audits to that of an observer; they should not interfere in a CRB's conduct of its audit on a client. In addition, they should ensure that they do not influence the outcome of a CRB audit, in any manner.

However, this should not prevent the AB assessors from being pro-actively involved in the process, by arranging intermediate briefings, or by asking for clarification and additional information, etc.. Clarifications, exchange of information, briefings etc. should preferably take place during planned breaks or separate meetings; however it may also be necessary to conduct them during ad hoc breaks or meetings. They should be conducted away from the presence of the CRB's client, to preserve AB to CRB confidentiality.

Note; any information collected during the witnessing of an audit is confidential and has to be treated by the ABs' auditors and staff accordingly.

AB auditors should avoid providing any opinions to the CRB, or to its client, while the audit is being conducted.

To be of maximum value, the AB auditors should attempt to cover the CRB's full client audit process at site.

AB auditors should try to ensure that their presence and witnessing activity is not perceived as interference by clients, and is instead viewed positively.

4. Feedback and reporting of results

Feedback on the CRB's performance should only be given to the CRB audit team when the audit is completed. Where possible, this should be planned to occur at the end of the audit, at the client's premises (away from the presence of the client).

The AB's auditors should produce a report on the witnessing of the audit only after receipt and review of the CRB's own audit report.

The report on the witnessing of the audit should avoid repeating details of the performance of the client's QMS and on the findings raised by the CRB audit team, as these should already be included in the CRB's report.

However, there may be situations where observations are made during the witnessing process, and which are not reported by the CRB's audit team, (e.g. that regulatory requirements are being contravened by the client or are not properly addressed by the client's QMS); the AB's auditors should inform the CRB's audit team about such observations during the post-audit feedback session, and should also record them as nonconformities in their report on the witnessing of the audit.

Where an AB's report includes nonconformities, it should require that action is taken by the management of the CRB to address the issues raised.

Similarly, if the observations clearly indicate that the auditing of the client's QMS shows such major deficiencies as to doubt the validity of the CRB's certification process (particularly during surveillance or re-certification audits), this should be properly recorded in the AB's report and duly addressed to the management of the CRB; additionally it should be submitted for further consideration and action within the AB.

Date: 30 July 2005

Accreditation Auditing Practices Group Guidance on:

"PROCESS APPROACH" BASED ACCREDITATION AUDITS

1. Introduction

Using the process approach during an accreditation audit provides added value to the accreditation activity since the body under evaluation will typically be using a process approach itself.

Although not being a direct requirement of ISO/IEC 17011, feedback from Certification and Registration Bodies (CRBs) has indicate a desire that the Accreditation Body (AB) assessors understand and be able to apply the process approach to their audit activity.

The value of and need for a process approach will be enforced by the publication of the forthcoming standard ISO/IEC 17021 which encourages CRBs to operate a formal quality management system (in line with the principles of ISO 9001:2000).

The process approach facilitates a focus on interested parties needs and expectations and provides a basis for continual improvement.

The process approach is based on the identification of the key processes related to the CRB activities and on their proper management and control.

For more information, reference can be made to recognized information sources, such as the standard ISO 9000:2000 *Quality management systems – Fundamentals and Vocabulary* and the ISO 9000 Introduction and Support Package: *Guidance on the Concept and Use of the Process Approach* for management systems , (document ISO/TC 176/SC 2/N544, available from http://www.iso.org/tc176/sc2).

2. CRB objectives

The ultimate objective of the CRB processes is to achieve a consistent attestation of the conformity of the client's QMS to the applicable requirements. The AB auditor should never loose sight of this overall objective.

Typical processes of CRBs needed to fulfil the above objective are:

Top management processes

- strategic planning
- management review (based on internal audits)
- management of complaints and appeals

Management of resources processes

- Information management
- Personnel (internal staff, auditors) qualification and monitoring

- Management of subcontractors (outsourced processes)
- Logistics

Product realization process

- Preparation of proposals
- Contract review
- Planning of certification program
- Scheduling of audits
- Allocation of audit teams
- Audit reporting
- Certification decision
- Invoicing
- Maintenance of certification
- Suspension and withdrawal of certification

Measurement, analysis and improvement processes

- Internal audits
- Performance analysis
- Monitoring of client and other interested parties' satisfaction, including emphasis on the final users of certified goods and services
- Other measurement and monitoring activities included in the main processes above

3. Application by an AB

An Accreditation Body should ensure that all its assessors have received sufficient training regarding the requirements in ISO 9001:2000, particularly those on the process approach, since this is the approach used by the assessed body in witness audits.

For the above processes, the following general aspects should be considered by the AB assessors:

- have the CRB's processes been identified and documented, including process objectives, and have related responsibilities been defined and assigned?
- have the relevant resources and information been determined and deployed?
- are methods in place to monitor and/or measure and analyse each process, including appropriate records, and has their validity been confirmed?
- is the issue of continual improvement of the effectiveness of the CRB operation properly addressed?

AB assessors have to be aware that the application of the process approach may be different from CRB to CRB, depending on the size and complexity of the CRB and its activities.

4. Example questions to be addressed by an AB during a process based audit

Note: References to the clauses of the applicable standards and guidance documents are implicit in the questions themselves. These can be aligned with the formal accreditation requirements.

What follows is applicable, in principle, to any kind of assessed process.

Process characteristics

- What are the processes needed for the CRB's QMS (see the list of typical processes of CRBs)
- Are any of these processes outsourced?
- What are the inputs/outputs for each process? Do they comply with the accreditation requirements?
- Who are the "customers" of the processes?
- What are the requirements of these customers?
- Who are the "owners" of the process?
- Are these owners competent for the job?
- How is the competency of the people involved in the process defined, assessed and maintained?

Criteria and methods

- What are the characteristics of intended results of the process? Do they comply with the accreditation requirements?
- What are the criteria for monitoring, measurement and analysis?
- How are these criteria incorporated into the planning of the processes?
- Are the business performance issues taken into proper account?
- Is there any impact on CRB impartiality and integrity?
- What methods are used for data gathering?

Resources

- What are the resources needed for the process? Are these resources appropriate and do they comply with the accreditation requirements?
- What are the communication channels?
- How is external and internal information about the process provided?

Feedback

- What data need to be collected?
- What records need to be kept?

Measurement, monitoring and analysis

- How is the process performance monitored (process capability, customer satisfaction)?
- What measurements are applied?
- How is the gathered information analyzed (statistical techniques)?
- How are the results of the analysis taken into account?

Date: 30 July 2005

Accreditation Auditing Practices Group Guidance on:

AUDITING THE COMPETENCE OF QUALITY MANAGEMENT SYSTEM CERTIFICATION/REGISTRATION BODY AUDITORS AND AUDIT TEAMS

1. Introduction

According to the requirements of ISO/IEC Guide 62 and the related IAF guidance documents, a CRB has to have a system in place to establish, evaluate, demonstrate and maintain the competence of the people involved in its entire certification process. An AB audit team should obtain evidence that this has been done and demonstrated, prior to recommending the granting of accreditation.

Auditing a CRB over the competence of its auditors involves two main aspects:

c) assessing whether the CRB has performed an evaluation of the competence it requires from its auditors in relation to the scope of its accreditation (this would involve assessing individual auditor qualifications, e.g. their education, training and experience);
d) ascertaining whether the CRB deploys a competent team of qualified auditors for each specific audit.

2. Evaluation of auditor qualifications and competence

ISO 19011:2002 defines "competence" as being the demonstration of personal attributes and knowledge and skill. Further, in Clause 7, ISO 19011:2002 states that for QMS auditors, competence is actually based on personal attributes together with generic knowledge and skills, and specific knowledge and skills.

(Note 1: Table 1 in ISO 19011:2002 has little to do with competence and should not be treated as if it establishes requirements for competence.)

Evidence of CRB auditor certification is neither required, nor sufficient in itself, as a factor of competence demonstration; this remains as the sole duty and responsibility of the CRB. Such certificates should not be dismissed nor accepted at face value by an AB auditor; instead the CRB's basis for approving its auditors' competency, their certification and the justification for awarding it, should be evaluated to see if they are satisfactory.

A CRB should be able to prove that its auditors have been evaluated, tested and that their competence has been properly demonstrated.

(Note 2: If an auditor has previously performed the role of an audit Team Leader [as defined in 19011:2002] this is no guarantee that they will be competent to perform an audit on a different organization. The role should not be considered as having a permanent status in itself).

a) Personal attributes

A CRB's auditor records should show that each of its auditors' personal attributes have been evaluated.

The evaluation can range, for example, from self-assessment evidence and simple observations, to more complex methods such as psychological analysis. What is important is that the method selected has the ability to promptly identify any shortfall. The CRB should then either correct the situation (through further development of the auditor(s) concerned), or mitigate and manage it, by only assigning the auditor to situations where the auditor and an audit will not be compromised.

b) Generic knowledge and skills

The most important aspect of generic knowledge and skills concerns management system principles and practices. It is also vital that an auditor has a proper understanding of the certification standard, in order to ensure valid and appropriate audit findings.

As far as audit principles, procedures and techniques are concerned, the relevant knowledge may result from successful completion of formal training courses and /or a CRB's specific training programme (e.g. skills may be developed from role play or from audits carried out under guidance or supervision).

The CRB should set the levels of knowledge and skills of quality related methods and techniques necessary to audit a QMS effectively. These should include modern quality management tools and their applications.

There should be evidence that the CRB's auditors have acquired knowledge of these competence components effectively, and that their performance has been demonstrated, tested and accepted, rather than just depending on records of completion or mere attendance on a training course.

A CRB auditor's knowledge and skills should be maintained and updated through continuing professional development.

c) Processes and products

Competence in processes and products i**s** the most difficult set of knowledge and skills for auditors to acquire (and the most troublesome for CRBs to apply).

Experience has shown that outdated or time expired workplace experience is often of limited value (and especially claims of having gained product and process knowledge through operating as a consultant; such claims need to be treated carefully).

The AB auditor should ascertain that the CRB has recognized that the auditor(s) will encounter sector specific terminology and jargon, technical characteristics of processes and products (including services), and very often unique sector specific processes and practices.

Whatever the approach taken, it is expected that the CRB has defined the parameters to be met in terms of the specific product knowledge and skills for use when establishing the requisite audit team profile.

The situations can often be very straightforward, with processes and techniques pertaining to well defined industrial activities; in others, they can be very complex (especially in fields such as food, aerospace, agriculture, finance or education. Examples of processes that require specific auditor competence are those for design and development).

The AB auditor should verify that the CRB has properly taken into account the risks associated with the products/processes or with the specific sector in itself, when assigning auditors. It may well be that in situations of high-risk the CRB decides that the audit team will always include competent technical experts. In cases of low risk, it may be that CRB auditor(s) without specific product and process sector knowledge may operate alone, but aided with the support of briefing notes.

In some situations it may be sufficient to have a simple mechanism based on qualification in a macro-discipline, such as mechanical engineering, electrical engineering, industrial engineering, or metallurgy. In other situations it may be more appropriate to consider more detailed disciplines such as a software-network expert, agro-biologist, food technologist, nutritionist, hygienist, materials scientist, etc.

CRB auditors may be able to acquire satisfactory levels of knowledge and skills to audit effectively in technical areas that are different from their mainstream industrial or commercial disciplines. This may be through methods such as auditing under the supervision of a competent auditor.

The same requirements for auditors on process and product knowledge and skills should also be applied to re-assessment and surveillance audits.

d) Sizes of organization

It is recognized that the knowledge and skills needed to audit a large corporate multi-site organization are different from those needed for small and medium enterprises (where employees are involved in several processes, with multiple tasks and functions). An auditor who is familiar with small or medium sized organizations will not necessarily be competent to audit large organizations, and vice versa.It is also important to consider cultural differences based on the size of an organization.

The CRB should avoid assigning an auditor without sufficient knowledge and skills of the appropriate size of organization.

The AB auditor should obtain evidence that the knowledge and skills to effectively handle these situations have been gained from appropriate means, including but not limited to, exposure to these organizations through training, work place experience and auditing experience under training and supervision.

e) Culture and Language

CRBs often need to assign auditors to perform audits in organizations that are based in different countries. The differences in language and culture may prevent effective audits from being performed.

CRBs should record the language abilities of their auditors, and the countries they have worked in.

Where it is not possible for a CRB to match an auditor to a particular language and culture for a client, it should ensure that supporting translators are available to assist during the audit. Preferably, such translators should be independent from the client. Additionally, it

would be useful for the auditor to be given relevant cultural guidance or training, prior to the audit.

The AB auditor should examine if these issues are addressed effectively by CRBs in their auditor assignment processes and, where translators are required, in their audit planning and preparation processes.

f) Legal, statutory, and regulatory requirements

CRB auditors should be aware of the applicable laws and other regulatory requirements that will have an effect on a QMS specific situation. The CRB should ensure that they are aware of such laws and regulations, and that they do not exceed their role in performing an audit.

3. Evaluation of competence requirements

For each audit, the CRB should establish a profile for the organization to be audited (in terms of the proposed scope of certification).

This should lead the CRB into defining and documenting the competence requirements for individual auditors and /or the audit team for that audit (based on the criteria in section 2 above).

The defined criteria need to be the minimum necessary to ensure satisfactory auditor performance and deliver audits that are sufficiently thorough and consistent, and which also provide added value.

4. Deployment of a team of competent auditors

For each audit, the CRB should be able to demonstrate that it has selected competent auditors or an audit team (from its existing pool of auditors), which match the defined competence requirements for that audit (see section 3 above).

However, it may be necessary for the CRB to include specific technical expert(s) on an audit team, in order to achieve a complete match between the two profiles. This should be taken into account by the AB auditor.

Some CRB pool auditors will not have the full range of knowledge and skills needed. The AB auditor should ascertain that the CRB has precautions built-in to its assignment processes, to confine their activity accordingly.

Date: 15 May 2006

Accreditation Auditing Practices Group
ISO 9001 Auditing Practices Group
Guidance on:

Auditor Code of Conduct and Ethics

1. Introduction

There can be no doubting the fact that Auditors are often seen to be in a very powerful and privileged position.

This document provides guidance on the points which need to be kept in mind and which if overlooked, might adversely affect an auditor's conduct and ethical behavior. This paper is especially relevant to all auditors when a code of conduct has not been specified under terms and conditions of contract with an employer. A typical Code of Ethics is also included.

2. General Statement

Auditors in promoting high standards of ethical conduct, **shall:**

1) act solely in the best interest of the employing organization, and its clients, in the performance of their duties;

2) conduct themselves professionally, with truth, accuracy, fairness and responsibility;

3) not misrepresent their qualifications, competence or experience, nor undertake assignments beyond their capabilities ;

4) treat in a confidential and private manner all information gained in relation to any of the organization's identified activities of accreditation and certification of specific organizations or individuals; unless authorized in writing to disclose such information by the organization, and the organization's client (when applicable), and

   - will not discuss such information with anyone except those who have a need to know the information for legitimate purposes of the accreditation, registration or certification processes;

   - will not disclose any details of audit findings, neither during nor after the audit process;

5) treat in a confidential and private manner all information gained in relation to any of the above entities' activities wherein such information may include, inter alia:

- any device, graphics, written material or other information in tangible or intangible form, clearly identified as “confidential”, relating to the activities of the organization;

- any device, graphics, written material or other information in tangible or intangible form, identifiable as private by the nature of its content and/or context;

6) Treat in a confidential and private manner all information which may be considered “confidential” when the prudent judgment of an organization could determine that such information is private and confidential to the organization, and recognize that the organization may receive information that is not identified clearly as confidential but which may be perceived as confidential.

7) Not intentionally communicate false or misleading information which may compromise the integrity of the accreditation, registration and certification processes or decisions therein.

8) Be able to act professionally under adverse pressure from their employer and organizations being audited

3. Example of a typical Code of Ethics

To uphold and advance the honor, dignity and integrity of the conformity assessment profession, and in keeping with high standards of ethical conduct, I acknowledge that I:

a) General issues

1) Will be honest and impartial, and will serve with devotion my employer, my clients, the public, and my identified organization.

2) Will strive to increase the competence and prestige of the auditing profession.

3) Will use my knowledge and skill for the advancement of human welfare, and in promoting the safety and reliability of products and services for public use.

4) Will earnestly endeavor to aid the work of my organization.

b) Relations with the Public

5) Will endeavor to aggressively extend public knowledge of the work of each organization and of its members that relate to the public welfare.

6) Will be dignified and modest in explaining my work and merit.

7) Will preface any public statements that I may issue by clearly indicating on whose behalf they are made.

c) Relations with Organization, Employer and Clients

8) Will act as a trustee for each organization, employer and/or client.

9) Will inform each organization, employer or client of any business connections, interests or affiliations which might influence my judgment or impair the equitable character of my services.

10) Will not disclose information concerning the confidential business affairs or technical processes of any present or former organization, employer or client without its proper consent.

11) Will not accept compensation from more than one party for the same service without the consent of all parties. If employed, I will engage in supplementary employment or consulting practice only with the consent of my employer.

d) Relations with peers (when applicable)

12) Will take care that credit for the work of others is given to those to whom it is due.

13) Will endeavor to aid the professional development and advancement of those in my employ or under my supervision.

14) Will not compete unfairly with others; will extend my friendship and confidence to all associates and those with whom I have business relations.

15) Will respect my peers opinion and conduct to ensure that honesty and openness is demonstrated within an audit team

16) Will react openly and professionally in the event of non-ethical behavior of my peers

Date: 8 December 2006

Accreditation Auditing Practices Group Guidance on:

Criteria for Competence of AB Assessors and Assessment Teams

This paper provides guidance on how to establish and evaluate competence requirements for assessors and assessment teams used by Accreditation Bodies (ABs) in order to improve the effectiveness of the accreditation process and foster the harmonization of the approaches followed by different ABs.

1. Competence criteria

In general terms, AB assessors should:

- be familiar with the relevant accreditation and conformity assessment standards and their AB's accreditation procedures;
- be suitably trained in the profession;
- have a good knowledge and understanding of different assessment methods;
- be appropriately experienced and skilled for the job.

Guidance on the application of the above criteria can be found in ISO 19011.

An AB assessor should be able to apply a process based approach to conducting assessments and should be capable of understanding the processes of an evaluated conformity assessment body (CAB) and in relating them to the requirements of relevant international standards and guides. Additionally, an AB's assessors should have the ability to trace back non conformities or deficiencies to the CAB's processes or management system (see the Accreditation Auditing Practices Group paper on *"Process approach" based accreditation audits*).

The AB shall have defined the criteria for the competencies needed to carry out accreditation assessments, including office assessments and witnessing activity, as required. The criteria may be differentiated between lead assessors, assessors and trainee assessors. The criteria should be based on the requirements of ISO 17011 and should be approved by the policy making body of the AB.

The competency criteria may be defined in terms of basic (generic) requirements and specific requirements (related to a particular scheme and sector and to other specific features).

In the following differing competency criteria are highlighted that an AB should consider when selecting its assessors and assessment teams for a particular assessment:

Basic (generic)

a) Procedures and standards

- Knowledge of the procedures of the AB,

- Knowledge of the AB standard (ISO/IEC 17011) and of the standards applicable to the assessed CABs (ISO/IEC 17021, ISO/IEC Guide 65, ISO/IEC 17024, ISO/IEC 17020) and related IAF guidance documents.
- Knowledge of ISO 19011.

b) Personal attributes (see ISO 19011)

The personal attributes of individual assessors should be evaluated using a variety of methods. The results should be used to determine the assignment of an assessor to a specific assessment or assessment team.

c) Generic knowledge and skills

- Ability to understand the business processes of a CAB and to assess such processes;
- Ability to formulate judgements.

Specific

d) Scheme/sector related and regulatory requirements

- Knowledge of management system (MS) standards, for MS certification accreditation schemes;
- Understanding/familiarity with products, processes and technologies related to the business activities (economical and social) covered by the accredited MS certifications;
- Knowledge of product standards, production technologies, use of products and related problems, for product certification accreditation schemes (*);
- Knowledge of applicable standards and know-how and skills of concern for the different professional figures, for personnel certification accreditation schemes;
- Knowledge and understanding of relevant tools and instructions in order to be able to determine if regulatory requirements are properly managed by the CABs as far as applicable.

(*) Similar requirements apply, with due adaptation, to the assessment for accreditation of inspection of products, processes, plants, designs, etc..

The above sectoral knowledge should be derived, by assessors/assessment teams, from:

* their direct working experience in the related industry/service sectors, or
* educational, research and standardization activity in the area, or
* consulting and audit activity, or
* combination of such elements.

When such knowledge is not adequate, assessors or assessment teams should be supported by experts.

e) Characteristics of the CAB that is due to be assessed

These characteristics should be taken into account when selecting assessors/assessment teams, e.g. the size of the CAB, the number of its operational units, the countries it operates in, etc..

f) Culture and language

These aspects should also be carefully considered when planning assessments and choosing assessors/assessment teams, being particularly critical for cross-frontier accreditation assessments (both office and witness audits).

Regarding the requirements for the assessment teams, the AB should ensure that the assessment team collectively has the competence needed for a particular assessment – with reference to points from a) to f) – including any specific technical competence that may be identified as needed. As already mentioned, it may be necessary to include experts in the team in case the specific technical expertise is not available by the assessors.

2. Qualification process

The assessor/expert qualification process should cover the initial selection, training, ongoing training and periodic evaluations that may be required to maintain and confirm continued competence. Assessors and experts need to be:

- selected (based on education, knowledge, experience and skills possessed);
- trained in the accreditation rules and methods and in the AB's accreditation procedures, criteria and any relevant provision, by suitable training courses or equivalent means;
- continuously monitored and evaluated by appropriate techniques (see ISO 19011).

Date: 19 January 2007

Accreditation Auditing Practices Group Guidance on:

Auditing Accreditation Scopes

This paper provides guidance on how Accreditation Bodies (ABs) should assess the competence of conformity assessment bodies (CABs) in view of granting a given accreditation scope, in order to promote the adoption of an effective and uniform approach and reduce the discrepancies among different ABs.

A key element of the accreditation process aims to assure that an accredited CAB is able to operate properly within its scope of accreditation, i.e. the types and fields of conformity assessment activities for which accreditation is sought by the CAB or has already been granted to it. *(Note: for formal definition of these terms, refer to ISO/IEC 17011)*.

This type of assessment is based on two fundamental kinds of evaluation:

- the analysis of the documentation of the CAB, and
- the observation of its practical behaviour.

The **documental analysis** should include, at least:

- a review of the documentation of the CAB that specifies the criteria for the competence of auditors and the selection of competent audit teams, including records of the conduct of competence analysis;
- a review of specific procedures, guidelines, check-lists, instructions etc. addressing specific requirements for the different conformity assessment activities included in the accreditation scope (if any);
- an examination of the procedures followed and the personnel available for the contract reviews, the allocation of resources and decisions concerning the issuance of applicable attestations of conformity (e.g. certifications);
- an analysis of records showing that the CAB has processes in place for the maintenance and review of the above criteria, on a periodic basis;
- an examination of documented evidence supporting the CAB's auditor competence.

The documental review should evaluate whether the criteria established by the CAB for auditor, or audit team, competence and selection have been based on analyses of the competence required to perform the applicable tasks.

The CABs auditor, or audit team, qualification process should be based on defined competence criteria and should, at least, take into consideration the following elements:

- Educational levels and study specialization;
- Work experience in the business sectors related to the scope, in order that the auditors are able to understand the characteristics of the relevant processes and products and applicable regulatory requirements;
- Demonstrated knowledge and skills acquired through audit activities, as a complement or an alternative to direct work experience, provided such audits

have been conducted in cooperation with an expert/auditor competent for the scope and that supporting evidence of this is available (e.g. from the certification files and records and evaluation report).

The review should also evaluate whether the documentation supporting individual auditor's competence – as indicated by their professional history – is consistent with the competence requirements established by the CAB.

Moreover, the review should determine whether the CAB has developed specific guidance (e.g. dedicated procedures or instructions) to aid the audit team in the specific fields falling within the accreditation scope and whether such guidance is effective in enhancing the competence of the audit team. The characteristics (type and extent) of such guidance should be based on the assessment of relevant risk factors by the CAB.

The **observation of the behavior** of the CAB in actual operation, should aim at:

- confirming that the procedures and criteria established by the CAB – for ensuring the competence of the auditors and for the assignment of competent teams – have been effectively and consistently implemented;
- determining whether the required competence is actually displayed during the assessments, both in conducting them and in reporting their results.

An audit at the offices of a CAB can only produce part of the evidence needed. This will require the AB to conduct accreditation witness audits to complete the assessment of a CAB's accreditation scope.

Accreditation witness audits are an effective tool to confirm the competence of a CAB and assist significantly in deciding whether or not to grant or maintain a requested scope of accreditation.

The choice of the number of witness audits to be undertaken before deciding on granting, or maintaining, accreditation depends on a number of factors which are left to the judgment of the AB; these need to be based on risk considerations.

Due attention should be given by the AB to the fact that the CAB may be displaying its best audit teams on the occasion of witness audits, which may be not indicative of the average competence level of the CAB. It is therefore recommended that the selection of the CAB auditors (and/or audit location) be made by the AB.

If, for any reason, the AB chooses to limit its witness activity, then the assessments at the CAB premises should be more extensive, e.g. they should include interviews with CAB's auditors to obtain at least "theoretical" confirmation of their ability to properly operate in the specific conformity assessment fields. Moreover, the examination of records (e.g. audit reports) should be as comprehensive and detailed as possible, since reading in and between the lines might help to judge the real competence of the compiler.

Date: 19 January 2007

Accreditation Auditing Practices Group Guidance on:

Auditing conformity with Annex 2 of the IAF's Guidance IAF GD2:2003 "Audit Times"

Putting forward the audit resources – i.e. number of competent auditors and time devoted to the audit –necessary to perform effective and reliable assessments of the compliance of the evaluated quality management system (QMS) with the applicable requirements is a key issue for ensuring the value and credibility of management system certifications and is a must for the conformity assessment bodies (CABs) operating in this field. This paper provides guidance on how Accreditation Bodies (ABs) should assess the proper accomplishment of these duties by the accredited CABs, based on IAF guidance.

When an AB assesses the conformity of the audit activities carried out be a CAB to the provisions of Annex 2 of IAF Guidance to ISO/IEC Guide 62, the AB's audit team should follow a process based auditing approach rather than a "check list" approach.

The AB's assessment should aim to determine whether a CAB perform its audits in accordance with its own procedures – which should themselves be based on the rationale of Annex 2 – and whether such procedures take into account the risks associated with:

- the product and processes covered by the audited QMS;
- the auditee's business sectors; and
- the size of the organizational and human resources involved in the QMS.

The IAF Guidance aims to define a framework for the CABs when establishing their audit criteria and makes recommendations on:

- the allocation of competent human resources (e.g. auditors);
- the use of appropriate procedures or instructions; and
- the allocation of appropriate time to perform an effective and reliable audit, depending on the audit conditions

The CAB's rules may allow these factors to be varied, depending on the knowledge, expertise and skills of its auditors.

Annex 2 is not intended to fix either the minimum or maximum audit times, in terms of manpower required, and should not be used, automatically and separately from the general context, both by the CAB and by the AB's audit team, when respectively seeking and assessing conformity with the intent of IAF Guidance regarding the conduct of effective audits.

The AB's audit team needs to determine whether the CAB has in place a process (or processes) to ensure that it allocates sufficient time and resources for the appropriate conduct of the audit, in all respects and in all circumstances, and whether the CAB can demonstrate that the process(es) is(are) effective.

Note that such a process could lead to the allocations of audit times which may be shorter than those derived from the Table of Annex 2, in some cases, but could also require longer audit times in other circumstances.

From an operational point of view, the accreditation assessment can be structured in three phases:

1. the verification of the soundness of the CAB process(es) (phase 1);
2. the evaluation of the understanding and correct application of such process(es) by the CAB's personnel (phase 2); and
3. the search for evidence of its(their) effective implementation, based on examination of records (phase 3).

Phase 1

This phase should aim at verifying that:

- the process(es) and procedures established by a CAB are based on the analytical approach described in Annex 2;
- the risks associated with an auditee's sector of economical activity have been properly identified and instructions are available to deal with them properly;
- the process takes due account of the CAB's experience acquired from auditing different sectors and different kinds of organizations (e.g. large versus small, national versus multinational, service industry versus manufacturing, etc..);
- the process has mechanisms in place to justify deviations from the numerical limits established by Annex 2 of the Guidance.

Phase 2

It should include an evaluation of whether:

- all the CAB's personnel involved in the process(es) have adequate knowledge and harmonized understanding of the process itself, including on the data and information to be collected and records to be prepared;
- the above personnel have been properly qualified to do their job.

Phase 3

This should include an examination of the records to confirm that:

a) the process(es) has(have) been realized according to the procedures established by the CABs;

   (Note: the AB's audit team should issue a non conformity if any violation of these procedures is found, regardless of the issue of the audit time duration in itself).

b) information is available to support the selection of audit times and to justify any departure from the audit times specified in Annex 2.

   The AB's audit team shall carefully review all the elements considered by a CAB when establishing its audit times and, in particular, the criteria that would support a deviation from the audit times indicated in Annex 2. The AB's auditors should especially examine cases where there has been a reduction in the allocated audit times, but should not exclude examining cases where longer times have been used.

In deciding if such allocations are reasonable, the AB's audit team should take into account the fact that the audit times should allow for a comprehensive examination of the audited QMS, as well as for the identification of possible problems related to critical areas and for providing, in general, added value to the auditee.

If the above elements and criteria are not documented or are found to be unclear or insufficiently justified or not in compliance with the rationale of Annex 2 and the general principles outlined above, then the AB's audit team shall issue a non conformity.

The AB's audit team should be wary of situations where it finds that a CAB's audit times are consistently in numerical agreement with the data given in the Table of Annex 2; in these circumstances, the AB's audit team should require the CAB to provide evidence that such times are really those needed for an effective assessment of the management system, focused on its substantial ability to consistently provide products and services complying with the customer and regulatory requirements.

Of course, if the audit times employed are shorter than those indicated in the Annex – unless very good reasons exist for such reduction and can be clearly and objectively demonstrated by the CAB's process – it is unlikely that the above requirements will have been fulfilled.

When presenting non conformities to the CAB's management, the AB's audit team should clearly state its reasons, based on an appropriate analysis of the CAB's process(es) and supported by the evidence of what it has found.

Confirmation of the adequacy of the CAB's conformity to the IAF Guidance, will be enhanced by conducting witness audit.

Date: 19 January 2007

Accreditation Auditing Practices Group Guidance on:

Auditing the CAB Impartiality Committee

This paper provides guidance on how Accreditation Bodies (ABs) should assess the compliance, with the applicable requirements, of the structure of the conformity assessment bodies (CABs) in charge of ensuring impartiality of their operation, in order to clarify recurrent doubts and foster the harmonization of the approaches followed by different ABs,

CABs providing management system (MS) certification are required to have a documented impartiality structure which safeguards impartiality within themselves and within their operation, e.g. an impartiality committee or equivalent organ.

The impartiality structure needs to involve the participation of all parties concerned with the development of policies and principles for the content and functioning of a CAB's certification / registration system.

The impartiality structure should be given the authority to review and require action on:

- the current and intended activities of the CAB,
- the competence of the key personnel and
- the potential risks associated to the CAB's operation.

Impartiality needs to be established at three levels within the CAB, for:

- Strategies and policies;
- Decisions on certification/registration;
- Auditing.

The impartiality structure is required to safeguard impartiality at all three levels and can be an independent structure or combined with the management function (as long as no single interest predominates). In order to ensure that no single interest predominates, there should be formal rules of procedure that establish the duties and rights of the members, e.g. rules for attendance, quorum and voting. The CAB management may be represented on the impartiality structure, given such safeguards against predominance.

One function of the impartiality structure is to ensure that commercial or other considerations do not prevent the objective provision of the certification services. This is particularly important when the commercial interests of the owners can have influence over the certification policies and decisions.

The impartiality structure and its formal rules of procedure need to be defined in the documents that establish the CAB's legal status or by some other means that prevents change that could compromises the safeguarding of impartiality. This could be through vesting authority to the impartiality structure for approval of policies and some significant procedures such as the rules of procedure for the operation of the impartiality structure itself.

A CAB should ensure that relevant interested parties are represented on its impartiality structure, with no single interest predominating. These include the CAB itself, regulatory authorities, NGOs (such as cultural associations, trade unions, etc.., depending on the type of certification scheme), consultants, academia, as well as the intermediate (industry) and final users (consumers) of the CAB's accredited conformity assessment services.

It is intended that this group be a high-level group with responsibility for ensuring impartiality and not be a predominantly technical/sector based group.

In particular, it is not expected that the composition of the group should reflect the range of technical expertise of the CAB. However, it can be supported in its operation by technical experts, as an when required.

The members of the group shall sign declarations of confidentiality and absence of conflicts of interests.

It is for the CAB to demonstrate the adequacy of the process for identifying and involving the relevant interested parties and for the impartiality structure itself to demonstrate the adequacy of their participation.

In order to enable provision of proper and impartial certification/registration, the management of the CAB should provide all the information required for the impartiality structure to perform their job, including, but not limited to, the reasons for:

- all significant decisions and actions, and
- the selection of persons responsible for particular activities in respect to certification /registration.

AB assessors should seek to verify the appropriateness of constitution and effectiveness of the operation of the impartiality structure by:

1. Checking its composition, the interests represented and the expertise brought to the impartiality structure (when necessary);

2. Verifying the observance of the documented terms of reference and rules of procedure and the way the structure achieves its tasks in general;

3. Considering the ability of the impartiality structure to intervene in a timely fashion in response to the changing needs of the CAB.

4. Evaluating the adequacy and effectiveness of the output from the impartiality structure.

5. Considering the content and accuracy of the management reports to the impartiality structure.

6. Ascertaining whether the CAB advises the impartiality structure on the results of external assessments and any recommendations made by the AB.

This could be achieved by:

- reviewing the agenda, the minutes or other documents from the meetings of the impartiality structure;

- checking the participation at the meetings (including the presence of technical or other specific expertise in the discussions, where necessary), and/or
- having AB representatives taking part in the meeting as observers.

Date: 25 July 2007

Accreditation Auditing Practices Group Guidance on:

KEY CRITERIA FOR ASSESSING THE COMPETENCY OF CRBs AND THEIR ABILITY TO DELIVER CREDIBLE RESULTS

This paper provides guidance on the key issues that Accreditation Bodies (ABs) need to examine during accreditation assessments of management system certifiction/registration bodies (CRBs), in order to deploy effective, output focused, accreditation approaches.

These key issues concern:

- the processes that CRBs use to manage their technical activities (particularly those processes that are used to ensure that competent auditors will undertake audits competently, within the scope covered by accreditation); and,

- the level of detail that CRBs require for audit reporting.

1. The competency management system of a CRB

The combination of processes and resources that a CRB uses to ensure that competent auditors will undertake audits competently represents its "competency management system".

Such a system will consist of elements for the management of resources in general, and elements for the deployment of resources for a given audit activity.

a) Management of resources

For the management of resources, a CRB's competency management system needs to address:

- how it conducts reviews of its technical activities to:
  - determine the competency needs for its auditors;
  - identify independent reviewers of audit reports;
  - identify evaluators of auditors' competency;
- the specification of competency criteria;
- the recruitment and training of auditors and technical experts;
- evaluations of demonstrated auditor performance against the specified competency criteria;
- the maintenance of auditor competence (including processes to monitor this on an on-going basis that also take into account relevant feedback from the independent reviewers/evaluators);
- professional development (improvement of competence).

b) Deployment of resources for a given audit activity

For the deployment of resources for a given audit activity, a CRB's competency management system needs to address:

- how it reviews client applications and determines the associated competency needs for the audit team;
- the selection and appointment of appropriate audit team members and technical experts (where required);
- the selection and appointment of appropriate independent reviewers/ evaluators.

The above processes should cover all the activities falling within the scope of accreditation, namely the different types of management systems (QMS, EMS, OHSAS, ISMS, FSMS, etc..) and, within them, the applicable technical activities. The level of requirements that a CRB will need to specify in its competency management system will be influenced by the complexity and risks of the products and processes involved in such technical activities.

Demonstration by a CRB that the above processes are in place and are suitably managed should give the AB confidence in the ability of the CRB to conduct rigorous audits.

Consequently, a CRB's competency management system will need to be thoroughly assessed by the AB, using personnel with specific technical knowledge of the activities to which the system is applied.

The AB assessments should:

- evaluate the competency management system for completeness against the criteria given above
- check the compliance of the CRB to the requirements of its competency management system, through an examination of relevant documents
- include interviews with the CRB's managers who are responsible for the different technical activities, as well as interviews of a sample of auditors assigned to such activities.

2. Audit reports

In order for a CRB to make appropriate, informed, decisions on certification, it is necessary that the results of audits are presented in audit reports to an adequate level of detail. Therefore, the quality of audit reports needs to be evaluated by the AB.

An audit report should include:

- a clear statement on whether or not the audited management system has the capability to consistently meet the objectives of the relevant standard(s).
- details of objective evidence to support its statement

Audit reports that consist merely of check-lists of the clauses of the standard(s) and minimal objective evidence of compliance, plus a few short audit notes, are not considered to be sufficient.

A CRB's requirements for audit reporting will need to be carefully assessed by the AB, to confirm the adequacy of its reports and also of the adequacy of its independent reviews. This may require the use of technical experts.

If the AB challenges the adequacy of an audit report and/or feels there is a need to seek further clarification, and there is evidence of the CRB's independent review having arrived at a similar conclusion, this should be taken as a positive indication of the effectiveness of the CRB's certification process.

Date: 25 July 2007

Accreditation Auditing Practices Group Guidance on:

AUDITING CERTIFICATION BODY (CB) MANAGEMENT SYSTEMS BASED ON ISO 9001:2000 (option 1, clause 10 of ISO/IEC 17021)

This paper provides guidance for Accreditation Bodies (ABs) on assessing the management systems of Certification Bodies (CBs) who choose option 1 of clause 10 of ISO/IEC 17021, in order to help improve the effectiveness of such assessments.

1. Introduction

Clause 10.1 of ISO/IEC 17021 requires that "*In addition to meeting the requirements of Clauses 5 to 9, the certification body (CB) shall implement a management system in accordance with either:*

a) management system requirements in accordance with ISO 9001 (see 10.2, option 1), or
b) general management system requirements (see 10.3, option 2)".

Note that it is a CB itself that decides which option to choose in implementing its management system. Also note that the standard does not state which option is recommended or given priority. The AB should not force the CB to adopt a specific option before or after receiving its application for accreditation.

The fact that a CB can choose between a type a) or type b) management system means that such a choice will have an impact on the assessment approach that the AB will need to take. The AB has to be prepared to assess whichever option is adopted by a CB.

Note: this paper is not intended to provide guidance on option 2.

2. The assessment approach of the AB

As part of its accreditation criteria, the AB should require the CB to make clear which option it has chosen under clause 10.

Irrespective of the differences in applicable requirements due to the different options, the AB should be able to provide an assessment team that is competent to make an assessment against the applicable requirements. If the AB assessment team does not have sufficient knowledge of the relevant standards (including ISO 9001 in the case of option 1), then it is unlikely that a competent assessment will be performed.

For a CB choosing option 1, the requirements of 10.2 apply in addition to clauses 5 to 9 of ISO/IEC 17021.

Specifically "*the certification body shall establish and maintain a management system, in accordance with the requirements of ISO 9001, that is capable of supporting and demonstrating the consistent achievement of the requirements of ISO/IEC 17021, amplified by 10.2.2 to 10.2.5".*

This means that the AB's assessment team is expected to be familiar with, and competent to audit, the requirements of ISO 9001 as part of its accreditation criteria for a CB adopting option 1.

While a CB may declare that it has chosen to go for option 1, it should not expect to be fully audited against ISO 9001 for an AB assessment as this is not required. An AB's assessment of a CB adopting option 1 is never intended for the certification of the CB against ISO 9001 by the AB.

On the other hand, assessing against only clauses 5 to 9 will not mean that the requirements of ISO/IEC 17021 are fully met. There are areas where partial assessment against ISO 9001 will also be necessary.

For example, in clauses 5 to 9, there are no requirements for a CB to perform internal audits or to implement corrective or preventive actions, but the CB is required to perform such activities, regardless of which of the two options it chooses.

In the case of option 1, the AB will need to assess the related CB's compliance strictly against the requirements of ISO 9001.

Moreover, in assessing compliance with the management system requirements of ISO 9001, the AB must take into account the fact that some requirements of ISO 9001 are "amplified" in option 1.

A CB adopting option 1 is required to be sufficiently knowledgeable of the "process approach" in establishing and implementing its management system, as this is fundamental to ISO 9001. The AB's assessors will also need to be familiar with the "process approach" in order to perform an option 1 assessment competently, and account should be taken of this in the approach that is adopted for the assessment.

Date: 14 October 2004

ISO 9001 Auditing Practices Group Guidance on:

The need for a 2 stage approach to auditing

Auditing ISO 9001:2000 requires auditors to obtain a good understanding of an auditee's quality management system (QMS) and the nature of its business. This is why it is beneficial for an organization to be visited prior to its certification audit and for a1st stage audit to be conducted.
This 1st stage audit is primarily for scoping and planning a certification audit (the stage 2 audit) and to allow the auditor to obtain an understanding of the organisation. For example, to gain knowledge of its QMS, policies, objectives, risks, processes, locations, etc. It is also may be used for the auditing body to communicate its needs and expectations to the auditee.
Activities performed at a preliminary 1st stage audit include:

- Identification of the key risks of the business and related statutory, regulatory aspects and compliance

- An assessment of whether the auditee's defined processes are adequate to meet its objectives and customer requirements

- Conducting a Documentation Review

- This review should determine if the organisation's QMS documentation adequately covers all the requirements of ISO 9001:2000. The review would normally be carried out at the auditee's premises (unless otherwise requested and justified). As a result of this activity, a report should be provided that notes any deficient areas. As part of the documentation review, the auditor should assess the extent and availability of supporting procedures and process descriptions. Collecting necessary information regarding the scope of the organization's management system, processes and location(s)

- Drafting the future certification documentation, including the Scope statement

- Planning the certification (stage 2) audit, including the requirements for audit team selection

- Obtaining evidence that internal audits and management reviews are being planned, or performed, effectively

- Checking that the QMS is implemented and ready for the stage 2 audit, including appropriate level of documents and supporting records.
  If the system is lacking in any way, the auditor should note this in the audit report, so that the organisation has an opportunity to rectify deficiencies prior to its certification (2nd stage) audit.
- Agreeing a date for the stage 2 audit

Date: 10 November 2004

ISO 9001 Auditing Practices Group Guidance on:

Identification of processes

1. Distinguishing between the concepts of a process and an activity

If an auditee cannot distinguish between the concepts of a process and an activity, the auditor can briefly explain the differences by using the guidance (clause 2.4) and definition (3.4.1) in ISO 9000:2000 as background information. The auditor must be able to adapt to the auditee's situation. It is the auditor's responsibility to understand the auditee's systems and approach.

During the audit, the auditor should determine whether there is a problem of difference of terminology only, or whether there is a lack of real implementation of the process approach by the auditee. There may be a need to issue an NCR if the auditee is not fully implementing the requirements stated in ISO 9001:2000, Clause 4.1. If this is simply a terminology problem, there should be no need to issue an NCR, if all the requirements of in Clause 4.1 are satisfied.

The auditee has the right to use its own terminology, provided the requirements of the standard are met. The auditor should mentally develop a cross-reference list to ensure consistency and better understanding.

2. A process has defined objective(s), input(s), output(s), activities, and resources

If the auditee does not understand that a process must have defined (but not necessarily measurable) objective(s), input(s), output(s), activities, and resources, the auditor should try reformulating the questions to the auditee avoiding the use of QM jargon, e.g. Can you explain to me your operations here? What are the basic jobs carried out in your department? What information do you need to start your work? Where does it come from? Who receives the result of your work? How do you know if you've done your job correctly? etc..

This should help the auditor to establish whether the processes (as per ISO 9001: 2000) are already defined, have clear inputs, outputs, objectives and so on.

3. Processes should be analysed, monitored and/or measured, and improved

If after applying the audit techniques outlined above, there is an absence of any records or other proof to demonstrate that the processes are analysed, and/or monitored, and/or measured, and/or improved, there would appear to be non-conformity with part of ISO 9001:2000 Clause 4.1.

4. The auditee/auditor considers that each clause or sub-clause of ISO 9001:2000 must be defined as a separate process

If the auditor considers this as the right approach, he should refer to relevant ISO documents, (notably the ISO/TC 176/SC 2 document N544 ISO 9000 Introduction and Support Package: Guidance on the Concept and Use of the Process Approach) which clearly indicates the contrary.

If the auditee considers this as the right approach, it is recommended that the techniques outlined in section 2 (above) should be used.

5. Is the process approach as described in the 'Introduction' to ISO 9001:2000 a requirement of the standard?

The description of the process approach in the 'Introduction' to ISO 9001:2000 is purely informative and does not introduce a set of additional requirements by itself. Clause 4.1 specifies the steps necessary to implement a process approach with regard to quality management system processes, the Note to clause 4.1 providing examples of processes needed for the quality management system. Audit methodologies must be oriented, accordingly, towards analyzing the processes of the organization.

Date: 14 October 2004

ISO 9001 Auditing Practices Group Guidance on:

Understanding the process approach

Helping an auditor to interpret the process approach

If an auditor does not understand or misunderstands the process approach, direct him or her to recognized information sources, such as the standard ISO 9000:2000 *Quality management systems – Fundamentals and Vocabulary* and the ISO 9000 Introduction and Support Package: *Guidance on the Concept and Use of the Process Approach* for management systems (document ISO/TC176/SC2/N544, available from http://www.iso.org/tc176/sc2).

A certification body/registrar should ensure that all its auditors have received sufficient training regarding the new requirements in ISO 9001:2000, particularly those on the process approach. Thus, an auditor should realise that several steps are needed, including the following:

- determining the processes and responsibilities necessary to attain the quality objectives of the organisation;
- determining and providing the resources and information necessary;
- establishing and applying methods to monitor and/or measure and analyse each process;
- establishing and applying a process for continual improvement of the effectiveness of the QMS.

The process approach concept must be so well understood by auditors that they are not limited by the terminology in the standard; however, auditees may use their own “in-house” terminology. Auditors must be aware that the application of the process approach will be different from organisation to organisation, depending on the size and complexity of the organisation and its activities. Special consideration should be given to the situation in small and medium enterprises (SME’s), so that auditors should not expect so many processes in their QMSs.

Helping an auditee to interpret the process approach

If an auditor is faced with a complete misunderstanding by an auditee, this situation should normally be identified at the 1st stage audit.

The auditor should refer the auditee to recognized information sources, such as those indicated in the section above. (In particular, the referenced ISO/TC 176/SC 2/N544 document sets out different steps in the process approach and provides useful guidance with examples).

The auditee should also pay sufficient consideration to

- the establishment of process objectives,
- process planning,

- the availability of suitable records.

Auditees frequently identify too many processes; some or all of them are activities, which do not fulfil the requirements of a process, in the sense that ISO 9001:2000 uses the concept. In this situation, an auditor should (in the 1st stage audit) propose that the auditee performs a redefinition of its processes, based on e.g. the criticality of the activities. This might be particularly relevant for SME's.

Date: 14 October 2004

ISO 9001 Auditing Practices Group Guidance on:

Determination of the "where appropriate" processes

Terminology

Where the terminology used by the auditee is different to that used by the auditor, the auditor should understand the concepts in ISO 9001:2000 using ISO 9000:2000 and make a mental or written cross reference between the terminology of the auditee and his/her own for the same concepts, avoiding the use of QM jargon.

The definition of process

If the definition of process is not interpreted in the same way by the auditor and the auditee, the auditor should seek to understand the auditee's point of view and not impose his own view unless it is clear (supported with enough objective evidence) that the requirements of the standard are not met. The same is true if the auditor believes that certain processes have not been correctly identified or are missing.

Exclusions

The auditor should refer to clause 1.2 of ISO 9001:2000, to the ISO/TC 176/SC 2/N524 document *ISO 9000 Introduction and Support Package: Guidance on ISO 9001:2000, Clause 1.2 'Application'* for further guidance, and the APG's guidance on Scopes.

The auditor should obtain objective evidence that the auditee cannot exclude a specific requirement, before reaching a conclusion.

It is good practice for an auditor to utilize the standard ISO 9000:2000 *Quality management systems - Fundamentals and vocabulary* and ISO/TC 176/SC 2/N524 as support documents, to explain the arguments to the auditee.

Date: 14 October 2004

ISO 9001 Auditing Practices Group Guidance on:

Auditing "where appropriate" requirements

The auditee should determine the application of the ISO 9001 "where appropriate" requirements, as this will affect its ability to satisfy its customers' requirements. (It may be useful to refer the auditee to ISO 9001:2000 clause 1.1 "… where an organization a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements".)

An auditor should ensure that the "where appropriate" requirements are really 'appropriate' in relation to the proposed/actual scope of the auditee's quality management system. Therefore the basis of audit should be against this criterion, which should form the benchmark when deciding what is appropriate or not.

Issues that should be considered include:

- Does this requirement add value to this element of confidence, without the 'where appropriate' being addressed?

- Does it increase the risk that the organisation cannot meet its customer requirements? (This may be more than a specific set of customer requirements, as it can include the demands and expectations of end users, consumers, or the supply chain).

Need for experience to make a judgement on a technical issue

An auditing body should be able to demonstrate that its auditor has the necessary sector knowledge, competence and auditing skills. The auditor needs to be able to demonstrate knowledge of a process that is being examined and to be able to apply their skill in evaluating whether the 'where appropriate' requirements are appropriate or not.

The auditor will need to understand how the 'where appropriate' requirements fit into the context of how a process is established and its expected outcomes. When the requirements are not considered to be "appropriate", the audit should provide objective evidence to demonstrate that the system is effective and that customer requirements are being consistently met.

An auditing body should have the necessary processes in place to ensure that an auditor has the specific skills for the organisation that is to be audited.

Date: 14 October 2004

ISO 9001 Auditing Practices Group Guidance on:

Demonstrating conformity to the standard

"Performing the audit to the standard's clauses" versus "Performing the audit to the auditee's processes"

When assessing conformity to the standard, audit checklists may not be sufficient

At the end of an audit, the auditor should be in a position to know whether all requirements of the standard are satisfied or not.

Trying to show compliance to a standard often brings people back to using checklists, where an auditor is able to check-off the requirements of the standard one-by-one, making sure that all the requirements have been covered. This basic approach of filling out a checklist is an easy way to ensure that all requirements of the standards have been checked. However, considering the approach of the ISO 9001:2000, performing an audit from a generic checklist might prevent an auditor from collecting evidence of effective interfacing between processes.

In some situations, completely moving away from the checklist (or audit question list) might not be possible, particularly if the organization needs to provide evidence of compliance to the standard to third parties (e.g. regulators, conformity assessment bodies).

It is important to use a checklist in an appropriate way and at an appropriate time, i.e. as a tool to help keep track of the requirements of the standard to be covered.

What is adequate sampling?

There is no statistical or mathematical formula to establish the right number of samples to be taken during an audit. Defining the number of samples (e.g. one, five, or even more samples of records for a particular requirement) to be taken to confirm conformity to the requirements is not efficient and does not ensure conformity. It is of course a fact that by increasing the number of samples taken, an auditor will have greater confidence regarding the actual status of the implementation of the QMS. "Adequate" sampling in this context would refer to a level of sampling taken during on-site interviews and record reviews that give sufficient confidence that the auditee's QMS is implemented as described.

Multi-site sampling, or sampling of the organizational units of a company, are covered in Annex II of the IAF's *Guidance on the Application of ISO/IEC Guide 62*, along with the required on-site auditor days and sampling formula for multi-sites.

The auditor needs to perform interviews and check records and evidence during the interview. The number of samples to be taken depends on the complexity of the process being audited, and on the quality of information received from the auditee during the interview. It is also important that the auditor maintains the schedule outlined in the audit plan. At the end of the day, the auditor needs to feel comfortable that the samples and the objective evidence seen are representative, in order to draw appropriate conclusions regarding the implementation of the QMS.

Recording audit information

ISO 19011 and the IAF Guidance on the Application of ISO/IEC Guide 62 explain what an audit report should contain. However, it is important that the audit reports to the auditee only contain important information for the auditee, e.g. information on possible improvements, positive observations, and non-conformities to the standard. Merely reiterating and explaining the requirements of the standard is unlikely to be what the auditee is looking for.

There may also be a requirement for the auditor to demonstrate the sequence in which the audit was performed, sometimes called the audit trail. Using audit notes is a very efficient way for an auditor to record the audit. The main disadvantage of using audit notes is that they tend to be a very personal way of recording information during an audit, and the levels of recording detail and styles will vary greatly from one auditor to another.

A checklist can ensure some uniformity in the performance of the auditors. However, auditors should never forget to spend their time auditing, not filling out checklists or taking notes.

Date: 14 October 2004

ISO 9001 Auditing Practices Group Guidance on:

Linking an audit of a particular task, activity or process to the overall system

The auditor should not lose sight of the overall direction of the audit, and get side-tracked by superfluous details. It is important that the auditor keep a close eye on the information provided by the auditee in the quality manual or documentation where the auditee has defined the interaction of processes. Interviews should also be performed in such a way that the auditors should determine the input and output of the process being audited. Keeping in mind the auditee's process map should ensure that the auditor will be able to determine the importance of the process he is auditing at any time, and will therefore be able to keep sight of the overall direction of the audit. This will also help the auditor to understand the linkage between the processes.

During an audit, the auditor has an opportunity to check the auditee's description of the interrelation of its processes. The auditor should take some samples to see if the descriptions are a proper reflection of the actual interrelation of the processes, as this will help determine if the process description is adequate.

Date: 14 October 2004

ISO 9001 Auditing Practices Group Guidance on:

Auditing Continual Improvement

How much improvement is "enough"?

It should be emphasised that the requirement in ISO 9001:2000 is for continual improvement of the *effectiveness of the QMS*.

Continual improvement emanates from the objectives set by top management, which should (at least) address: the improvement of internal efficiency (for the organization to remain economically competitive), individual customer needs, and the level of performance that the market normally expects.

For example, in the aeronautical sector, the "acceptable rate" of non-conforming delivered product is zero percent, so it would not be useful for the organization to set objectives for an "improvement" in this rate. However, it would be useful for the organization to have objectives aimed in improving its internal efficiency and its competitiveness (e.g. through innovation).

The auditor should seek to determine if the auditee has attempted to set objectives that establish the correlation between the 3 factors of: corporate objectives, customer needs, and market expectations. Thereafter, it is up to the organization to balance the need for improving internal efficiency and the need to progress with external performance (although the two are very often closely related). No one in isolation can ever be considered as being "enough" or "not enough".

One area which can be problematic for the auditor is to know what is a reasonable market benchmark. Continuing the above aeronautical example, if the organization announced that it had improved from a level of 50% non-conforming product delivered to 40%, this would demonstrate continual improvement, but would hardly be acceptable, given the industry sector's zero percent normal rate. However, if it announced that it had set an objective to improve its performance from 0,50% to 0,40%, this would be much nearer the market norm.

The only real solution for the auditor is to verify how the organization has determined this proposed rate of improvement, how it has evaluated the associated risks, and how this relates to customer requirements and the monitoring of feedback on customer satisfaction. It would be almost impossible to issue an NCR that stated "There was not enough continual improvement".

What sort of information is relevant and where can we find it?

The auditor has to verify how the overall corporate objectives have been translated into internal requirements throughout the appropriate processes, and how these requirements are communicated and monitored. So, the auditor should look for evidence that the organization is analysing data from process monitoring, and is then taking the results forward for evaluating process efficiency and/or improving process output. One point that should be specifically examined, is the consistency of the way in which the improvement of

any one process contributes to meeting the overall objectives, in order to ensure that this will not cause conflict in the achievement of other objectives.

The type of information that an auditor needs to look for, is evidence of how the corporate objectives are translated into specific QMS objectives. For example: an organization could set an objective to reduce customer complains by 30%. The top management analysis shows that 50% of the complaints concern overdue deliveries. The auditor should then look for evidence that the organization is monitoring and analysing key aspects of its scheduling and planning activities, throughout its processes, and the process interfaces, to reduce delays.

Improvement of the process or improvement of the QMS?

An auditor should remember that it would be unrealistic to expect an organization to make progress all potential improvements simultaneously. Each improvement will require the commitment of resources, which may need prioritisation by top management, especially where investments are needed. Instead, the auditor should seek to ensure that the improvement objectives are consistent overall, and are coherent with the trilogy of factors mentioned above. However, an organization that does not have a policy and objectives relating to continual improvement is clearly not complying with the standard. Similarly, the absence of any evidence of improvement on at least one of these aspects would have to be considered as indicating that an organization's quality policy is not in line with ISO 9001: 2000.

One word of warning: There is no requirement that the organization should set objectives for improvement of all its processes at any one time. As in the above example on reducing customer complaints, some processes may not be deemed by top management to contribute significantly to the reduction of delays, and it is only normal therefore, that the organization would not concentrate on these areas.

If the top management has set a (realistic) objective for a process, and there is no evidence of improvement, this information must be fed back into the management review so that top management can decide what type of action is appropriate - for example, re-adjusting the objective or providing other means to impact on the process.

Date: 14 October 2004

ISO 9001 Auditing Practices Group Guidance on:

Auditing a QMS which has minimum documentation

There can be disagreement between an auditor and an auditee on the absence of certain documented procedures, when the auditee presents only a quality manual and the six documented procedures specifically required by ISO 9001:2000.

The differences in view between the auditor and the auditee can arise from differences in the interpretation of the ISO 9001 requirements contained in Clause 4.2.1, and the related Note, which state:

"4.2.1 General
The quality management system documentation shall include:
….
d) documents needed by the organization to ensure the effective planning, operation and control of its processes.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to
a) the size of organization and type of activities,
b) the complexity of processes and their interactions, and
c) the competence of personnel."

The auditor should requests information on the auditee's operating processes and subsequently ask questions, record answers and observe staff at all levels (including administrative personnel, process owners and operators), to confirm that the actual working status conforms to the descriptions given.

Thereafter, the necessity for any documentation should be evaluated in the light of the observed need for consistency, and the role that any documentation could play in avoiding any significant, identified risks.

The reader is referred to the advice given in document referenced “ISO/TC 176/SC 2/N 525, *ISO 9000 Introduction and Support Package: Guidance on the Documentation Requirements of ISO 9001:2000*”

Date: 14 October 2004

ISO 9001 Auditing Practices Group Guidance on:

How to audit top management processes

Recognizing that the auditing of top management is a sensitive issue, this document provides guidance for this category of auditing.

Auditors should involve top management in the audit, i.e. invite them to opening and closing meetings, allow sufficient time in the audit plan for interviewing top managers, discuss audit findings directly with them, seek evidence of their commitment, etc.. It is important to change the focus of attention from just the quality manager to the top management of the organization.

The auditor should consider top management activities to be processes, and should auditing them accordingly.

Planning stage

The auditor needs to identify top management processes, and

a) understand the organization and its management structure, by reviewing information such as organization charts, annual reports, business plans, company profiles, press releases, websites,

b) make provision on the audit plan for gathering relevant information regarding top management commitment, directly from and by interviewing top management,

c) understand the culture of the organization and its top management, in order to determine its impact on the audit plan – and make appropriate adjustments.

d) take a professional approach in the auditor's own appearance, by determining the dress code of the organization.

e) plan the timing of the top management interview, to ensure convenience and punctuality.

An auditor with limited auditing experience should not be assigned to interview top management,

Conducting the audit

Common methods of evaluating top management commitment are:

1. Interviews with top management

The auditor can, by utilising business terminology appropriate for the top management, ask relevant questions that

a) seek to obtain evidence of top management's awareness of and commitment to quality and its relevance to the organization's overall objectives and management system,

b) establish evidence of conformity to the ISO 9001 requirements for management responsibility.

2. Collecting and corroborating evidence

The auditor/audit team should be constantly looking for opportunities to corroborate the answers received from top management when interviewed.

This includes

a) the availability and relevance of policies and objectives

b) the establishment of linkage between the policies and objectives

c) obtaining the evidence that these policies and objectives are effective and understood throughout the organization

d) determining if the policies and objectives are appropriate for continual improvement of the quality management system and for the achievement of customer satisfaction.

e) determining if top management are involved in management reviews.

Additional interviewing and gathering of evidence may be needed to provide the necessary corroboration.

The audit team should ensure that any additional evidence of top management commitment is also collected.

The auditor/audit team should review the collected evidence, to ensure the completeness and accuracy of the information, and to provide confidence in the conclusions drawn.

Audit reporting

Auditors should prepare their audit reports in order to make them appropriate for presentation to the top management of organizations. It may be appropriate to present an executive summary of the audit report, suitable for presentation to the top management and key interested parties of the organization. The executive summary should highlight the key findings, both positive and negative, and identify opportunities for improvement.

Date: 14 October 2004

ISO 9001 Auditing Practices Group Guidance on:

The role and value of the audit checklist

Introduction

This document provides information on the role and use of audit checklists to actively support the audit process.
Whilst the document is primarily directed to external auditing organizations (including registration and certification bodies), the information can also equally be used by any organization conducting internal audits.

Need for checklists:

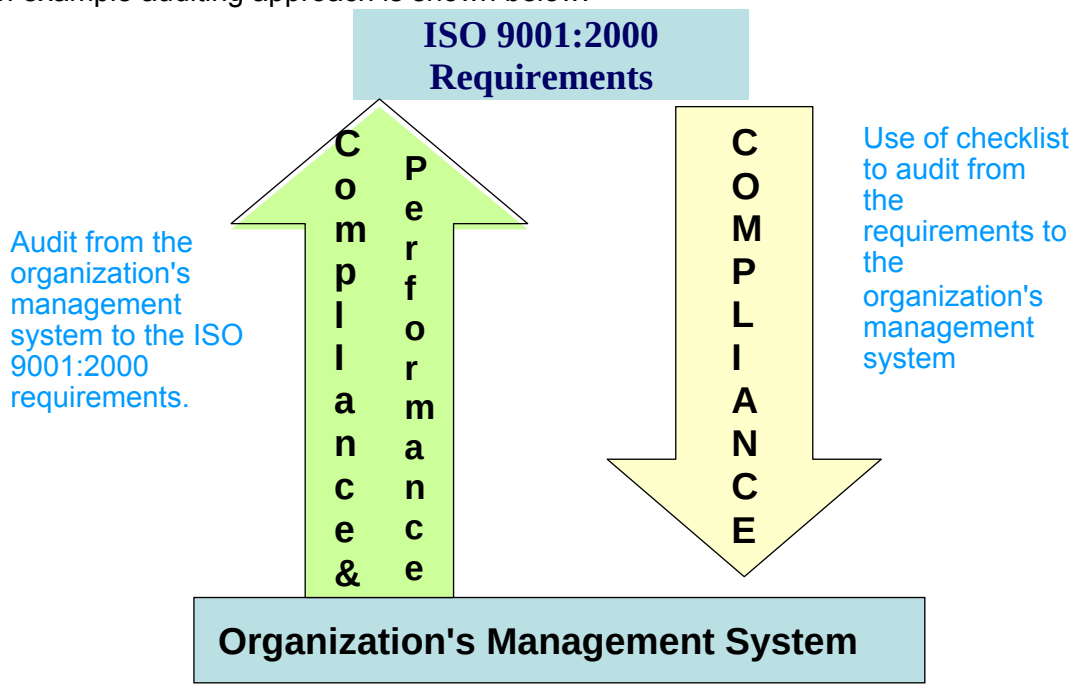
In looking at current auditing standards, ISO 19011 makes reference to "Preparing work documents" in Clause 6.4.3. The following is an extract from this clause:
"The audit team members should review information relevant to their audit assignment and prepare work documents as necessary for reference and for recording audit proceedings. Such documents may include

- *Checklists and audit sampling plans, and*
- *Forms for recording information, such as supporting evidence, audit findings and records of meetings.*

The use of checklists and forms should not restrict the extent of audit activities, which can change as a result of information collected during the audit"

The use of audit checklists:

Whilst not always required in management system standards, audit checklists are just one tool available from the "auditors toolbox". Many organizations will use them to ensure that the audit at a minimum will address the requirements as defined by the scope of the audit.
An example auditing approach is shown below:



It is beneficial to audit from the organization's quality management system up to the requirements. A checklist may be used to ensure that all relevant ISO 9001 requirements addressed

Advantages:

Literature available in the marketplace notes the following with respect to the use of audit checklists:

1. Checklists if developed for a specific audit and used correctly:
    a. Promote planning for the audit.
    b. Ensure a consistent audit approach.
    c. Act as a sampling plan and time manager.
    d. Serve as a memory aid.
    e. Provide a repository for notes collected during the audit process (audit field notes)
2. Audit checklists need to be developed to provide assistance to the audit process.
3. Auditors need to be trained in the use of a particular checklist and be shown how to use it to obtain maximum information by using good questioning techniques.
4. Checklists should assist an auditor to perform better during the audit process.
5. Checklists help to ensure that an audit is conducted in a systematic and comprehensive manner and that adequate evidence is obtained.
6. Checklists can provide structure and continuity to an audit and can ensure that the audit scope is being followed.
7. Checklists can provide a means of communication and a place to record data for use for future reference.
8. A completed checklist provides objective evidence that the audit was performed.
9. A checklist can provide a record that the QMS was examined.
10. Checklists can be used as an information base for planning future audits.
11. Checklists can be provided to the auditee ahead of the on-site audit.

Disadvantages

In contrast, when audit checklists are not available, or poorly prepared, the following issues/concerns are noted:

1. The checklist can be seen as intimidating to the auditee.
2. The focus of the checklist may be too narrow in scope to identify specific problem areas.
3. Checklists are a tool to aid the auditor, but will be restrictive if used as the auditor's only support mechanism.
4. Checklists should not be a substitute for audit planning.
5. An inexperienced auditor may not be able to clearly communicate what he/she is looking for, if they depend too heavily on a checklist to guide their questions.
6. Poorly prepared checklists can slow down an audit due to duplication and repetition.
7. Generic checklists, which do not reflect the specific organizational management system, may not add any value and may interfere with the audit.
8. Narrow focused checklists minimize unique assessment questions/approach

Conclusion

There are advantages and disadvantages in using audit checklists. It depends on many factors, including customer needs, time and cost restraints, auditor experience and sector scheme requirements. Auditors should assess the value of the checklist as an aid in audit process and consider its use as a functional tool.

Date: 24 November 2004

ISO 9001 Auditing Practices Group Guidance on:

Scope of ISO 9001:2000, Scope of Quality Management System (QMS) and the Scope of Registration/Certification

The **scope of ISO 9001:2000** is given in clause 1 *Scope*, and defines the scope *of the standard itself*.

This should not be confused with the ***scope of the QMS***, which is a term commonly used to describe the organization's processes, products (and /or services), and related sites, departments, divisions etc., to which the organization applies a formal QMS. (Note, this does not necessarily include all the processes, products, sites, departments, or divisions etc. of the organization).

The ***scope of the QMS*** should be based on the nature of the organization's products and their realization processes, the result of risk assessment, commercial considerations, and contractual, statutory and regulatory requirements.

While ISO 9001:2000 is generic and is applicable to all organizations (regardless of their type, size or product category), under certain circumstances, an organization may exclude complying with some specific ISO 9001:2000 requirements (from clause 7), while being permitted to claim conformity to the standard. This is because it has been recognized that not all the requirements in this clause of the standard are relevant to all organizations. ISO 9001:2000 itself makes allowance for such situations, through clause 1.2 *Application*.

Consequently, the ***scope of registration/certification*** encompasses the **scope of the QMS**, as well as describing any excluded ISO 9001 requirements.

As the terms **scope of the QMS** and **scope of registration/certification** are often used interchangeably, this can lead to confusion when a customer or end user is trying to identify what parts of an organization have been registered/certified to ISO 9001, what product lines or processes are covered by the QMS, or what ISO 9001 requirements have been excluded.

In order to dissipate such confusion and to enable identification of what has been registered/certified, the scope of registration/certification should clearly define:

- the scope of the QMS (including details of the product lines and related sites, departments, divisions etc. that are covered by it),
- the organization's main processes for its product realisation or service delivery activities (such as design, manufacture and delivery), for the product lines that are covered,
- any ISO 9001 requirement that has been excluded

(It should be noted that the scope of registration/certification is not the same as the ***certificate*** that is awarded to the organization after successful demonstration of conformity to ISO 9001. The certificate will usually include a synthesized description of the scope of registration/certification, but not the details of the ISO 9001 requirements that have been excluded; however, it may include a note to refer to the fact that the exclusions are detailed in the organization's Quality Manual.)

It is essential that a scope of registration/certification be drafted by the organization prior to applying for registration/certification. This should then be analysed by the CRB during the Stage 1 audit, for appropriate planning of the Stage 2 audit (see the guidance on "The need for a 2-stage approach to auditing").

It is responsibility of the auditor:

- to ensure that the final statement of the scope of registration/certification is not misleading;
- to verify that this scope only refers to the processes, products, sites, departments, or divisions etc. of the organization that were assessed during the registration/ certification audit; and
- to verify that this scope defines any excluded requirements from ISO 9001, and that justification for such exclusions is provided and is reasonable.

As an additional measure to combat potential confusion among customers and end users, the scope of registration/certification should be clearly defined in the organisation's Quality Manual and any publicly available documents (this includes, for example promotional and marketing material).

However, promotional statements should never be included in the scope of registration/ certification itself.

ISO/TC 176/SC 2 has developed document N524 the *ISO 9000 Introduction and Support Package: Guidance on ISO 9001:2000, Sub-clause 1.2 'Application'* to provide users with information regarding the intent of ISO 9001:2000 clause 1.2 Application, including some typical examples of its use in practical situations. (N524 is available for free download from www.iso.org./tc176/sc2). Additionally, the IAF has published its IAF Guidance on the Application of ISO 9001:2000, Issue 2, which should also be referenced.

Date: 14 October 2004

ISO 9001 Auditing Practices Group Guidance on:

How to add value during the audit process

What do we mean by "adding value"?

We hear so much about the importance of "adding value" during quality management systems (QMS) audits, but what does this really mean? Is it possible to add value without compromising the integrity of the audit or providing consultancy? In principle, all audits should add value, but this is not always the case.

This document provides guidance on how an audit can add value for the different parties involved, and the various situations that are likely to be encountered in the context of second or third-party audits.

"Value-added" quality management systems

There are several dictionary definitions of "value", but all focus on the concept of something being ***useful. "Adding value"*** therefore means to make something ***more useful.***

Some organizations have used the ISO 9000 series of standards to develop quality management systems that are integrated into the way they do business, and are ***useful*** in helping them to achieve their strategic business objectives – in other words they ***add value*** for the organization. Conversely, other organizations may have simply created a bureaucratic set of procedures and records that do not reflect the reality of the way the organization actually works, and simply add costs, without being useful. In other words, they do not "add value".

It is a question of approach:

> A non-value-added approach asks "What procedures do we have to write to get the ISO 9000 certification?"
>
> A "value-added" approach asks the question "How can we use our ISO 9001:2000-based quality management system to help us to improve our business?"

How to add value during the audit process?

How can we ensure that an audit is ***useful*** to an organization in maintaining and improving its QMS?(We should recognize, however, that there may be other perspectives that need to be taken into consideration.)

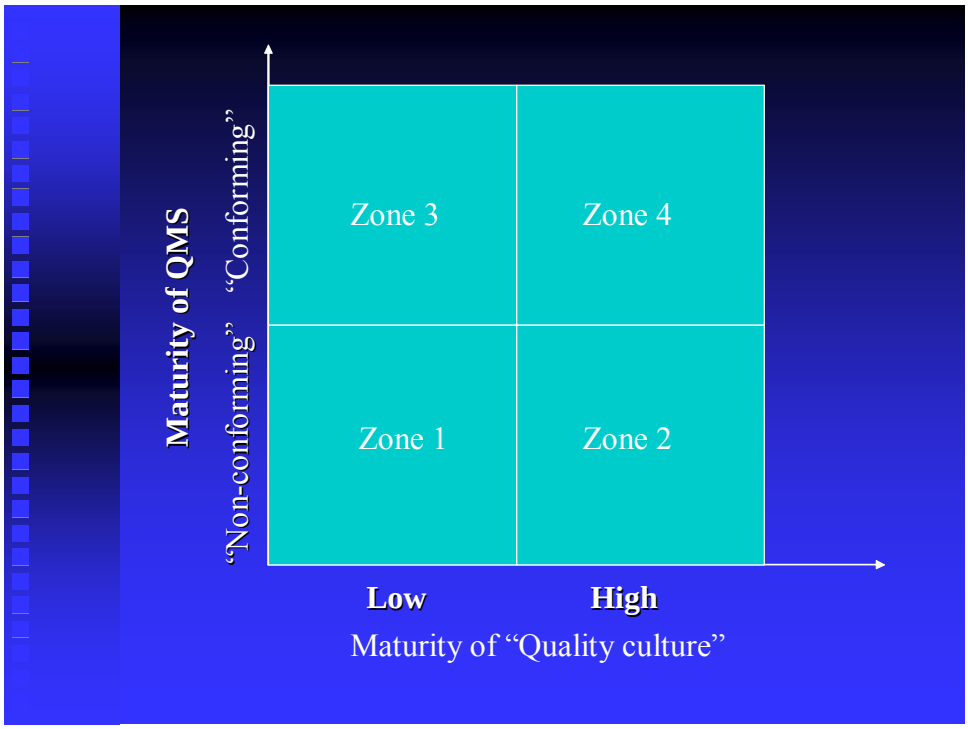
In order to "add value", a third-party audit should be useful:

- to the certified organization
  - by providing information to top management regarding the organization's ability to meet strategic objectives
  - by identifying problems which, if resolved, will enhance the organization's performance.

- by identifying improvement opportunities and possible areas of risk
- to the organization's customers by enhancing the organization's ability to provide conforming product
- to the certification body, by improving the credibility of the third party certification process.

The approach to "adding value" is likely to be a function of the level of maturity of the organization's quality culture and the maturity of its QMS, with respect to the requirements of ISO 9001:2000.

By referring to Figure 1, we can conceptually separate organizations into four different zones, as follows:



Zone 1: (Low maturity of "quality culture"; immature QMS, not conforming to ISO 9001:2000)
Zone 2: (Mature "quality culture"; immature QMS, not conforming to ISO 9001:2000)
Zone 3: (Low maturity of "quality culture"; mature QMS, conforming to ISO 9001:2000)
Zone 4: (Mature "quality culture"; mature QMS, conforming to ISO 9001:2000)

It is important to note that in this context:

"**Quality culture**" refers to the degree of awareness, commitment, collective attitude and behaviour of the organization with regard to quality.

"**Conformity to ISO 9001:2000**" relates to the maturity of the organization's QMS, and the extent to which it meets the requirements of ISO 9001:2000. (It is recognized that specific minor nonconformities might be detected even in organizations that show an overall high degree of maturity and conformity to ISO 9001:2000.)

Zone 1: (Low maturity of "quality culture"; immature QMS, not conforming to ISO 9001:2000)

For an organization that has little or no "quality culture" and a QMS that does not conform to ISO 9001:2000, the expectation of how an audit might add value could mean that the organization would like to receive advice on "***how to***" implement the quality management system and/or resolve any non-conformities raised.

Here the auditor has to take great care, because in a third party audit such advice would certainly generate a conflict of interest, and would contravene the ISO/IEC Guide 62 requirements for the accreditation of certification bodies. What the auditor ***can*** do, however, is ensure that whenever non-conformities are encountered, the auditee has a clear understanding of ***what*** the standard requires, and ***why*** the non-conformity is being raised. If the organization can recognize that resolving these nonconformities, will lead to improved performance, then it is more likely to believe in and commit to the certification process. It is important, however, that all identified non-conformities ***are*** reported, so that the organization clearly understands ***what*** needs to be done in order to meet the requirements of ISO 9001:2000.

While some organizations might not be totally satisfied with an audit outcome that does not result in certification, the organization's customers (who receive the organization's products) will certainly consider this to have been a "valuable" audit from their perspective. From the perspective of the certification body, failing to report all detected nonconformities and/or providing guidance on ***how to*** implement the quality management system, adds no value to the credibility of the auditing profession or the certification process.

We must recognize that the above discussion relates mainly to third party (certification) audits. There is no reason why a second party (supplier evaluation) audit should not "add value" by providing guidance to the organization on how to implement its quality management system. Indeed, under these circumstances, such guidance (if it is well-founded), would undoubtedly be useful for both the organization and its customer.

Zone 2: (Mature "quality culture"; immature QMS, not conforming to ISO 9001:2000)

For an organization that has a mature "quality culture", but an immature QMS that does not conform to the ISO 9001:2000 requirements, the basic expectation of how an audit might add value will probably be similar to that of Zone 1. In addition, however, the organization is likely to have a much higher expectation of the auditor.

In order to be able to add value, the auditor has to understand the way in which the organization's existing practices meet the requirements of ISO 9001:2000. In other words, understand the organization's processes in the context of ISO 9001:2000, and not, for example, insist that the organization redefine its processes and documentation to align to the clause structure of the standard.

The organization might, for example, base its management system on business excellence models, or total quality management tools such as Hoshin Kanri (Management by Policy), Quality Function Deployment, Failure Mode and Effect Analysis, "Six-sigma" methodology, 5S programmes, Systematic Problem Solving, Quality Circles and others. In order to add value during the audit process, the auditor should, at a minimum, be aware of the organization's methodologies, and be able to see to what extent they are effective in meeting the requirements of ISO 9001:2000 for that particular organization.

It is also important that the auditor not be "intimidated" by the organization's apparent high degree of sophistication. While the organization may be using these tools as part of an overall total quality philosophy, there might still be gaps in the way the tools are being employed. Therefore, the auditor must be able to identify any systematic problems and raise the appropriate non-conformities. In these situations, the auditor might be accused of being pedantic or even bureaucratic, so it is important to be able to demonstrate the relevance of the non-conformities that are being raised.

Zone 3: (Low maturity of "quality culture"; mature QMS, conforming to ISO 9001:2000)

An organization that has been certified to one of the ISO 9000 series of standards for a significant period of time might be able to demonstrate a high level of conformity to ISO 9001:2000, but at the same time not have truly implemented a "quality culture" throughout the organization. Typically, the QMS might have been implemented under pressure from customers, and built around the requirements of the standard, rather than on the organization's own needs and expectations. As a result, the QMS, may be operating in parallel with the way the organization carries out its routine operations, generating redundancy and inefficiency.

In order to add value in these circumstances, the primary objective of the auditor should be to act as a catalyst for the organization to build on its ISO 9000-based quality management system, and to integrate the system into its day-to-day operations. While the third party certification auditor cannot provide recommendations on how to meet the requirements of ISO 9001:2000, it is acceptable and indeed good practice to ***encourage*** and ***stimulate*** (but not ***require!***) the organization to go ***beyond*** the requirements of the standard. The questions the auditor asks (and the way he or she asks those questions) can provide valuable insights for the organization into how the QMS could become more efficient and ***useful***. Identification of "Opportunities for Improvement" by the auditor should include ways in which the effectiveness of the QMS might be enhanced, but could also address opportunities for improved ***efficiency***.

Zone 4: (Mature "quality culture"; mature QMS, conforming to ISO 9001:2000)

For an organization that has a mature "quality culture", and has been certified to one of the ISO 9000 series of standards for a significant period of time, the expectation of how an audit might add value will be the most challenging for an auditor. A common complaint among this kind of organization is that the "routine surveillance visits" by the auditor may be superfluous, and do little to add value in the organization's eyes.

In these cases, top management becomes an important customer of the certification process. It is therefore important for the auditor to have a clear understanding of the organization's strategic objectives, and to be able to put the QMS audit within that context. The auditor needs to dedicate time for detailed discussions with top management, to define their expectations for the QMS, and to incorporate these expectations into the audit criteria.

Some tips for the auditor on how to add value

1) **Audit planning:**

    a. Understand the auditee's expectations/corporate culture
    b. Any specific concerns to be addressed (output from previous audits)?

c. Risk analysis of industry sector / specific to organization.
d. Pre-evaluation of statutory/regulatory requirements
e. Appropriate audit team selection to achieve audit objectives
f. Adequate time allocation

2) Audit technique:

a. Focus more on the process, and less on procedures. ***Some*** documented procedures, work instructions, check-lists etc. may be necessary in order for the organization to plan and control its processes, but the driving force should be process performance.

b. Focus more on results and less on records. In a similar fashion, ***some*** records may be necessary in order for the organization to provide objective evidence that its processes are effective (generating the planned results) but in order to add value, the auditor should be aware of and give credit for other forms of evidence.

c. Remember the 8 Quality Management Principles

d. Use the "Plan-Do-Check-Act" approach to evaluate the organization's process effectiveness.
   i. Has the process been planned?
   ii. Is it being carried out according to plan?
   iii. Are the planned results being achieved?
   iv. Are opportunities for improvement being identified and implemented?
      — By correcting non-conformities
      — By identifying root causes of problems and implementing corrective action
      — By identifying trends, and the need for preventive action
      — By innovation

e. Adopt a "holistic" approach to evidence gathering throughout the audit, instead of focusing on individual clauses of ISO 9001:2000.

3) Analysis and decision

a. Put the findings into perspective (Risk assessment / "common sense").

b. Relate findings to the effect on the organization's ability to provide conforming product (see ISO 9001:2000 clause 1.1).

4) Report and follow-up

a. Sensible reporting of audit findings
   i. Different approaches may be required depending on:
      - the organization's maturity (Zones 1, 2, 3 and 4)
      - the level of confidence in the organization's QMS
      - the risks involved
      - the auditee's attitude and commitment to the audit process
         - Proactive
         - Reactive
   ii. Ensure that any cultural aspects are taken into consideration
   iii. Emphasize positive findings as appropriate

iv. Will the solution proposed by the organization in response to negative findings be ***useful***?

b. Reports should be objective and focused on the right “audience”. (Top management will probably have expectations that are different from those of the management representative).

Date: 14 October 2004

ISO 9001 Auditing Practices Group Guidance on:

Auditing 'competence' and the 'effectiveness of actions taken'

The following information is provided to guide auditors performing certification audits in understanding the ISO 9001:2000 clause 6.2.2 requirements for 'competence' and 'effectiveness of actions taken', e.g. training.

These requirements are usually audited as part of a product realization process audit and not in isolation. However, it is recognised that some organizations will have separate human resource processes, where most of the evidence needed can be found.

This document identifies typical activities performed by organizations to ensure the competence of their personnel and to evaluate the effectiveness of actions taken to satisfy those competence needs, and gives guidance to auditors regarding the types of evidence they should aim to find, and provide examples where appropriate.

To satisfy the competence/effectiveness requirements of ISO 9001:2000, an organization will typically need to do several things:-

- Identify what competencies are required by personnel performing work which affects quality
- Identify which personnel already performing the work have the required competencies
- Decide what additional competencies are required
- Decide how these additional competencies are to be obtained – training of personnel (external or internal), theoretical or practical training, hiring of new competent personnel, assignment of existing competent personnel to different work
- Train, hire or reassign personnel
- Review the effectiveness of actions taken to satisfy competence needs
- Periodically review competence of personnel

Throughout the process, the organisation is required to maintain appropriate records of education, training, skills and experience. However, ISO 9001:2000 does not specify how the process will be established or the exact nature of the records to be maintained.

In auditing an organisation's compliance with the competence and training evaluation requirements, an Auditor would typically be seeking evidence that the following issues are addressed:-

1 - An organisation needs to identify what competencies are required by personnel performing work that affects quality.

> **Guidance** - The objective of the auditor should be to determine whether there is a systematic approach in place to identify these competencies and to verify that the approach is effective. The outcome of the process may be a list, register, database, human resources plan, competencies development plan, contract, project or product plan, etc.

Discussions could initially be held with top management to ensure they understand the importance of identifying the competencies required. These may also be a potential source of information regarding new or changed activities or processes, which may lead to different competency requirements in the organization.

A review of competencies might also be needed when a new tender or contract is being considered. Evidence of this could be found in related records. Competence requirements may be included in contract documents where the activities of subcontractors can have an impact on processes and/or product quality characteristics.

Auditors need to determine whether the organisation has identified new or changed competence needs during surveillance audits.

2 – Are competent people assigned to those work place activities necessary to control the quality characteristics of its processes and products?

Guidance - Verify that some form of evaluation process is in place to ensure that the competencies are appropriate to the organization's activities, and that the personnel selected as competent are demonstrating these competencies. Also, the process should ensure that any deficiencies are being acted upon and the effectiveness of personnel is being measured. Verify that the activities that affect quality are performed by persons selected as competent. Evidence may be obtained throughout the audit with an emphasis on those processes, activities, task and products where human intervention may have the greatest impact. The auditor may review job descriptions, testing or inspection activities, monitoring activities, records of management reviews, definition of responsibilities and authorities, nonconformity records, audit reports, customer complaints, processes validation records etc.

3- The organization needs to evaluate the effectiveness of the actions taken to satisfy the competence needs

Guidance - The organization may use a number of techniques including role-play, peer review, observation, reviews of training and employment records and/or interviews (see ISO 19011, Table 2, for further examples). The appropriateness of a particular evaluation method will depend on many factors. For example, training records could be viewed to verify that a training course had been successfully completed (but note, this alone would not provide evidence that the trainee is competent). However, this same method would not be acceptable to evaluate whether an auditor performed satisfactorily during an audit. Instead, this may require observation, peer review, interviews, etc.. The organization may need to demonstrate the attainment of competence of its personnel through a combination of education, training and/or work experience.

4 – Maintenance of competence.

Guidance – The auditor needs to verify that some form of effective monitoring process is in place and being acted upon. Ways of doing this include a continuing professional development process (such as the one described in ISO 19011), regular appraisals of personnel and their performance, or the regular inspection, testing or auditing of product for which individuals or groups are responsible. Ongoing changes in competence requirements may indicate that an organization is proactive in maintaining personnel performance levels.

Date: 12 December 2005

ISO 9001 Auditing Practices Group Guidance on:

Auditing statutory and regulatory requirements

ISO 9001:2000 requires an organization to identify and control the statutory and regulatory requirements **applicable to its products (including services).** It is up to the organization how to do this within its QMS.

The organization should demonstrate that the statutory and regulatory requirements applicable to its products / services have been properly identified, are available and easily retrievable.

Auditors need to be aware of the general and specific statutory and regulatory requirements applicable to the products/ services included within the scope of the QMS. During the audit preparation phase, auditors should obtain relevant information from internal or external sources with respect to these statutory and regulatory requirements. This will allow them to make a judgment on the suitability of the QMS to address such requirements. These requirements need to be identified and integrated in the resource management and product realization activities of the organization.

During the audit phase, auditors should:

- ensure that the organization has a methodology in place for identifying, maintaining and updating all applicable statutory and regulatory requirements;
- ensure that these statutory and regulatory requirements are utilized as 'process inputs' while monitoring 'process outputs' for compliance with requirements;
- ensure that any claimed compliance to standards, statutory and regulatory requirements etc. are properly demonstrated by the organization;
- if evidence is found, during the audit, that specific information regarding statutory and regulatory requirements has not been taken into account, the auditors should issue a nonconformity;
- auditors should also issue a nonconformity if a non compliance with such requirements is directly identified.

Auditors should avoid making statements about what statutory or regulatory requirements are applicable to the products / services of the organization, or about methods of compliance, because of the possibility of liability.

Nonconformities should be issued only in situations where identification has been made of system deficiencies or of direct violations in respect of statutory and regulatory requirements applying to the products/ services of the organization.

However, if nonconformance with other kinds of statutory requirements (e.g. health and safety, environment, etc.) is co-incidentally, detected during the audit, this fact cannot be ignored by the audits. It should be reported without delay to the auditee and, if required, to the audit client.

If auditors become aware of any deliberate legal non-compliance that could affect the image and credibility of the QMS before, during, or after the audit (including, for example, breach of antitrust law, labour law, health and safety or environmental regulations) then this should be taken into consideration and investigated further, as appropriate. Apart from the regulatory authority's action, it is for the auditors to assess the effectiveness of the QMS in meeting customer requirements (stated or generally implied) and report this to the certification/registration body management to take appropriate actions.

Date: 12 December 2005

ISO 9001 Auditing Practices Group Guidance on:

Auditing Quality Policy, Quality Objectives and Management Review

1. Auditing quality policy

The quality policy and its effective deployment can only be truly assessed based on the overall results of the audit.

Audit methods should include:

- Interviewing Top Management to understand their approach and commitment to quality; (click here to link to the guidance paper on the auditing of Top Management processes)

- Evaluating, through the records of management review, the commitment and involvement of Top Management in the establishment, implementation, monitoring and updating of the quality policy;

- Assessing whether Management has effectively "translated" the quality policy into understandable words and guidelines at all levels of the organization, with corresponding objectives at each applicable function / level;

- Conducting interviews with personnel to verify if they have the required awareness, understanding and knowledge of the way the organization's quality policy **relates to their own activity,** regardless of the terms used by such people to express their understanding;

- Seeking evidence of effective dissemination of the quality policy by appropriate communication.

2. Auditing quality objectives

Auditors need to verify that the organization's overall quality objectives have been defined, that they reflect the quality policy, are substantially coherent, aligned and compatible with the overall business objectives, including customer expectations. If this is not the case, the auditors should further evaluate Top Management commitment to quality.

The fulfilment of quality objectives needs to be measurable and documented.

There is no specified way of identifying or documenting quality objectives, as these may appear through business plans, management review outputs, annual budgets, etc. It is up to the auditors to satisfy themselves that the objectives are adequately documented.

The auditors should obtain evidence of the way the quality objectives are suitably cascaded throughout the organization's structure and processes, linking the general strategic objectives to management objectives and down to specific operational activities.

It is recommended that the documented quality objectives should be examined at the documentation review stage of the audit.

Before the end of the audit, the auditors have to satisfy themselves that the quality objectives are realistic and relevant, and that the organization has assigned to responsible personnel the resources needed to meet their objectives. Evidence of this should be obtained at all levels of the organization.

Quality objectives are not static and need to be updated in the light of the current business climate and the quest for continual improvement. Auditors should verify that the overall performance of the organization reflects the aims of the quality policy and reasonably meets the quality objectives.

Auditors should keep in mind that the fulfilment of objectives can be measured in a quantitative or qualitative manner. They should also remember that there is a clear link between the dynamic aspects of revising the quality policy and the quality objectives and the commitment of the organization to continual improvement.

3. Auditing Management Review

ISO 9001:2000 requires top management to review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. The review could be carried out at a separate meeting but this is not a requirement of the standard. There are many ways in which top management can review the quality management system such as receiving and reviewing a report generated by the management representative or other personnel, electronic communication or as part of regular management meetings where issues such as budgets and targets are also discussed.

The management review is a process that should be conducted and audited utilizing the process approach.

ISO 9001 clause 5.6.2 specifies the inputs to the management review process and these topics shall be included. However, these are not the only subjects that can be included in a review. They might not be addressed individually or simultaneously but as part of an overall review of the business. Auditors should be aware that inputs could be in many forms such as reports, trend charts and so on.

As output from the management review process, there should be evidence of decisions regarding:-

- change of quality policy and objectives,
- plans and possible actions for improvements,
- change of resources,
- revised business plans,
- budgets.

Output is not only related to improvements or changes but could include decisions on other important issues such as plans to introduce new products.

Records of management reviews are required but the format of these is not specified. Minutes of meetings are the most common type of record, but electronic records, statistical charts, presentations etc. could be acceptable types of records.

The management review process might also include elements of quality management system planning where changes to processes and systems are being considered. Where this is the case, the auditors should review whether or not the following points have been considered:-

- Will changes to the management system or business as a whole have an impact on other parts of the system or business?
- Are proposed changes evaluated before implementation?
- In preparing strategic plans, are issues such as those in 4.1 of the standard considered?
- Are the controls needed identified before the outsourcing of a process is begun?

The management review process should not be an exercise carried out solely to satisfy the requirements of the standard and the auditors; it should be an integral part of the organization's business management process. The overall management review is complex process carried out at various levels in the organization. It is always a two-way process, generated by top management with inputs from all levels in the organization. These activities could vary from daily, weekly, monthly, organizational unit meetings to simple discussions or reports.

Auditors should look for evidence that the inputs and outputs of the management review process are relevant to the organization's size and complexity and that they are used to improve the business. Auditors should also consider how the organization's management is structured and how the management review process is used within this structure.

Date: 15 May 2006

ISO 9001 Auditing Practices Group Guidance on:

Auditing the control of monitoring and measuring devices

The following information is provided as guidance for auditing the processes associated with control of monitoring and measuring devices, and to assist in the evaluation of justifications for the exclusion of clause 7.6 from the scope of an organization's quality management system**.**

In the auditing of monitoring and measuring processes, it is important for auditors to understand the difference between "*monitoring*" and "*measuring*":

- *monitoring* implies observing, supervising, keeping under review (using monitoring devices); it can involve measuring or testing at intervals, especially for the purpose of regulation or control.
- *measuring* considers the determination of a physical quantity, magnitude or dimension (using measuring equipment).

While "measuring equipment" is defined in ISO 9000 clause 3.10.4 as "*measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realize a measurement process",* the standard only requires "measuring equipment" to be calibrated when it is used for measuring purposes "…*to provide evidence of conformity of product to determined requirements"* either by product or process measurements.

Equipment and devices may be used for indication, monitoring or measuring. The same equipment could be used for all these three functions.

For example, in some industries, a pressure gauge may be used:-

- as an indicator (e.g. to ensure that the pressure is present);
- as a monitoring device (e.g. to ensure that the pressure is stable and the process is under control); and
- as measuring equipment (e.g. where the accurate value of the pressure is important for the quality of product).

However, the level of control depends on the intended use and determines whether or not it should be calibrated or validated. The depth and degree of such confirmation may vary, depending on the nature of products, services and related risks.

In cases where the organization makes use of measuring equipment, evidence should be obtained that the metrological needs related to the production or service processes have been properly identified/specified and that the measuring systems have been designed and are operated and maintained in such a way as to fulfil the applicable metrological needs.

Auditors should confirm that, in addition to providing the necessary calibration records and assuring the related measurement uncertainty and traceability, the organization is aware of

and has implemented, as appropriate, a metrological confirmation system as described in ISO 10012 adequate to the extent and types of the measurements performed.

Some organizations such as Hotels, Restaurants, Education Centers, Consultants, Public Services, among others, perform monitoring and measuring activities utilizing as "monitoring or measuring devices" surveys, examination papers, questionnaires, statistical reports, etc, due to the nature of their product.

These "devices" should be controlled and validated accordingly to ensure that they provide consistent means of monitoring and measurement of the processes, product/service and customer satisfaction.

It is appropriate to address these "devices" whilst auditing conformance with clause 8.2 "Monitoring and Measurement". If an organization can demonstrate appropriate controls of such devices under this clause, an auditor needs to realize that not all the requirements related to Clause 7.6 may be applicable for such "devices".

The auditor needs to understand how the organization performs process control and the impact that the information, obtained from using these "devices", has on this process control.

When the impact is relevant, auditors should evaluate issues such as:

- How the organization validates that "the monitoring and measuring device" is consistent with the monitoring and measurement requirements.
- How the organization assures the information validity.
- The competence of the responsible to design "the monitoring and measuring device"
- How the organization validate the consistency of the results

From the description above, the organization should be able to decide whether or not all or part of the requirements of clause 7.6 may be excluded. It is stressed that just because an organization does not have measuring equipment that needs to be calibrated does not mean that it can automatically exclude compliance with the whole of clause 7.6; to do so would require that it also does not use any monitoring devices or monitoring equipment.

Additional explanation and examples are given in the ISO Handbook: *ISO 9001:2000 for Small Businesses – What to do, Advice from ISO/TC 176.*

Date: 14 October 2004

ISO 9001 Auditing Practices Group Guidance on:

Making effective use of ISO 19011

ISO 19011:2002 *Guidelines for quality and/or environmental management systems auditing* replaces the old ISO 10011 series of quality management systems auditing standards and provides guidelines for first, second and third-party auditing of both quality and environmental management systems. Whilst much of the standard is relevant to third party QMS audits, not all of its clauses are directly applicable. The standard contains options relating to auditing methods and auditor competence but the content is not mandatory. The guidance is intended to be flexible and the application can differ according to the size, nature and complexity of the organisation to be audited. It is up to each third party auditing body to use the guidelines to the extent appropriate to their needs and relevance to their own working practices.

The standard is divided into a number of sections including the following:

Principles of auditing

An auditor should be familiar with the 5 principles of auditing and apply them to the audit process.

Managing an audit programme

This will generally be the responsibility of the management of a third party auditing body and not an individual auditor. Auditors should be aware that audit programmes are monitored and reviewed at appropriate intervals. Auditors should provide input for improvement of audit programmes.

Audit activities

This guidance emphasises the importance of and the techniques for planning, conducting and reporting an audit and is of particular relevance to an auditor. Auditors should be very familiar with the guidance in Section 6 of ISO 19011 on these issues.

Competence and evaluation of auditors

The guidance on the competence and evaluation of auditors gives new emphasis to the importance of team competence as well as that of the individual, which replaces the prescriptive qualification criteria for auditors that were formerly set out in ISO 10011-2.

Competence is now defined as "*demonstrated personal attributes and demonstrated ability to apply knowledge and skills*". Less importance is now placed on prescribed levels of education, workplace and auditing experience and numbers of completed audits. These are now used as inputs to the knowledge and skills necessary for auditor competence.

Much of this guidance will be used by third party auditing bodies when setting their own competence criteria for auditors. However, individual auditors should be aware of the content of this section so that they can maintain, improve and work within the limits of their professional competence.

Practical help can be found throughout the guidelines and provides examples and additional clarification on various topics, although some may not be applicable to third party auditing.

Date: 14 October 2004

ISO 9001 Auditing Practices Group Guidance on:

Auditing customer feedback processes

1) Introduction

The customer feedback process is a critical part of the quality management system, and should therefore receive adequate attention during a third party audit. Feedback from the customer is one of the primary performance indicators that can be used to judge the overall effectiveness of the QMS. It is important, therefore, for the auditor to verify that

a) the organization's customer communication channels promote an adequate awareness of the process by which customers can provide feedback
b) inputs to the customer feedback process include relevant, representative and reliable data,
c) this data is analyzed effectively, and
d) the output from this process provides useful information to the management review and other QMS processes, to enhance customer satisfaction and drive continual improvement.

2) What are the requirements?

2.1) The overall objective of ISO 9001:2000, as stated in clause 1.1 is to specify requirements for a quality management system where an organization:

a) needs to demonstrate its ability to ***consistently provide product that meets customer and applicable regulatory requirements***, and
b) aims to ***enhance customer satisfaction*** through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

2.2) Clause 7.2.3 requires the organization to ***"****determine and implement effective arrangements for communicating with customers in relation to……customer feedback, including customer complaints."*

2.3) Clause 8.2.1 of ISO 9001:2000 states:

"As one of the measurements of the performance of the quality management system, the organization shall ***monitor information*** *relating to* ***customer perception*** *as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined."*

The ISO/TC176 guidance document on terminology (ISO/TC176/SC2/N526R) emphasizes that ***monitor*** means "to observe, supervise, keep under review; measure or test at intervals". It is important for auditors to recognize that there is no specific requirement in ISO 9001:2000 clause 8.2.1 for the organization to perform formal customer satisfaction surveys, or other measurements of customer satisfaction, though this could of course be a useful tool in monitoring customer perceptions. It is therefore important that the organization tries to see things from the customer's perspective, and ***monitors the***

customer's perceptions; ***measurement*** of customer ***satisfaction*** may be appropriate in some situations, but it is not a direct requirement of the standard.

NOTE: In addition to these specific references to the customer feedback process, there are a number of indirect references throughout the whole of the standard, which the auditor needs to take into account. Examples include feedback as part of the design and development process, process validation and others.

3) What should be addressed when auditing customer feedback processes?

Customer feedback is a ***process***. It needs to be ***audited*** as a process, not as a "clause of the standard". An evaluation also needs to be performed on the way in which the process is managed (see ISO 9001:2000 clause 4.1.c), and its ability to provide meaningful information with which to judge the ***overall*** effectiveness of the QMS. The way in which the organization obtains this feedback ("the method") is up to the organization to define.

The auditor should therefore be aware of the many factors that can affect the organization's approach, and should recognize that there is no fixed "recipe". Due consideration should be given to factors such as:

- organization size and complexity
- degree of sophistication of products and customers
- risks associated with the product
- diversity of customer base

3.1) Prior to the audit of the customer feedback process (preparation stage)

The auditor needs to be aware of the specific characteristics of the organization's products that are likely to impact customer satisfaction. Throughout the audit the auditor should be alert for indications that may suggest customer satisfaction or dissatisfaction which could serve as input into the audit of the customer feedback process. Good sources of such information may include, for example:

- Goods returned by the customer;
- Warranty claims;
- Revised invoices;
- Credit notes;
- Articles in the media;
- Consumer websites;
- Direct observation of, or communication with the customer (for example in a service organization).

3.2) During the process assessment

These are some of the issues an auditor should address during an audit of the customer feedback process:

a) What is the desired output of this process? What information is actually ***available*** on customer perceptions? How is this information used by management to drive improvements to the product, processes and the QMS?

- Are all customer categories covered by this information? It is important to remember that the organization may have more than one category of customer - see the definition of "customer" in ISO 9000:2000 clause 3.3.5. For example, a manufacturer may sell to wholesalers, who then sell to retailers, who in turn sell to the general public. In this case the organization may need to address all three types of customer and they may all have different perceptions. The organization could be satisfying one group and upsetting another.

b) ***How*** is the data collected to feed the process?

- There are many ways for an organization to monitor its customers' perceptions, and the auditor should avoid preconceived ideas about how this should be done. Some examples of techniques the organization can use include:
  - face-to-face evaluations, which may be appropriate in many service organizations such as hotels – "*How was your stay with us?*" or restaurants "*I hope you enjoyed your dinner*"
  - telephone calls or visits made periodically or after delivery of products and services,
  - questionnaires or surveys carried out by the organization itself, or by independent market researchers
  - other contacts with customers, for example by service or installation personnel
  - internal enquiries among the organization's personnel who are in contact with customers,
  - evaluation of repeat business
  - monitoring accounts receivable, warranty claims, etc.
  - customer complaints analysis

Often complaints are the only ***spontaneous*** feedback received from customers, and these should be analysed for any trends, key concerns, impacts etc. It must be stressed, however, that customer complaints can not be the only input for monitoring customer perceptions. Also, the auditor should avoid reaching conclusions only by looking at specific individual complaints - these should always be put in the context of their overall impact on the QMS.

c) How reliable is the information?

- In an ideal world, the organization would monitor the perceptions of all customers, but the costs of doing so might be prohibitive. Therefore it is necessary to verify the criteria the organization has used for any sampling of its customers, to ensure that this is representative, and reflects the risks both to the organization and its customers.
- The auditor should seek to verify the information provided by comparing with other evidence obtained during the course of the audit (see 3.1).
- In some cases it may be appropriate for the auditor to verify information directly with the organization's customers, though a certain diplomacy will be required when doing this

d) How is the data analyzed?

- Simply collecting data on customer perceptions is not sufficient – the auditor must follow the process through, to check how the data is analyzed (see ISO 9001:2000 clause 8.4), and what conclusions are made with respect to the effectiveness of the QMS.
  - Are there any trends?
  - Is the situation stable, improving, or deteriorating?
  - Are customer needs and expectations changing?
- Although it is not a requirement of ISO 9001:2000, it may be appropriate to ask the organization about industry comparisons, or benchmarking activities, in order to put customer feedback into perspective

e) How does the information generated by this process feedback into the QMS as a whole?
   - Organizations should be using the results of the customer feedback process to trigger corrective and/or preventive actions and as one of the overall measures of the QMS performance. The way in which these processes interact should also be subject to audit.
   - The auditor should be able to recognize that the output from the customer feedback process forms an important input into other QMS process, such as data analysis, management review and continual improvement processes.
   - An auditor who strives to add value will try to ensure that the organization recognizes the benefits a sound customer feedback process can bring, and will encourage (but can not require) the organization to think beyond simply "meeting the requirements of the standard"

f) What are the links to other QMS processes?
   - The auditor should recognize that the customer feedback process has important links and interfaces with several other QMS process that include, but are not limited to the following clauses of the standard:
     — 5.6 Management review
     — 7.5.2 Process validation
     — 7.2.3 Customer communication
     — 7.3.6 Design and development validation
     — 7.3.7 Design and development changes

Date: 10 February 2005

ISO 9001 Auditing Practices Group Guidance on:

Documenting a Nonconformity

The focus of any management system audit is to determine if the management system has been developed, is effectively implemented, and is being maintained. An organization becomes registered/certified on the basis that it has effectively implemented a management system that conforms to the requirements of ISO 9001: 2000. So, the emphasis of a management system audit should be on verifying conformity, not on documenting nonconformities.

Auditors should maintain a positive approach and look for the facts, not faults. However, when the audit evidence determines that there is a nonconformity, then it is important that the nonconformity is documented correctly.

What is a nonconformity? According to the definition in ISO 9000: 2000 (3.6.2), a nonconformity is "***non-fulfillment of a requirement***".

There are three parts to a well-documented nonconformity:

- **the audit evidence** to support auditor findings;
- **a record of the requirement** against which the nonconformity is detected;
- **the statement of nonconformity.**

While all of these need to be addressed, in actual practice, it is the audit evidence that is the first part to be identified and documented. This is because a competent auditor will observe situations that he or she "feels" may be a potential nonconformity during an audit, even though he or she may not be 100 percent certain at that point in time. The competent auditor will then document the audit evidence for the potential nonconformity in his/her audit notes, before pursuing additional audit trails, in order to confirm if it actually is a nonconformity.

If there is **no** audit evidence – there is **no** nonconformity. If there **is** evidence – it **must** be documented as a nonconformity, instead of being softened with another classification (e.g. "observations", "opportunities for improvement", "recommendations", etc.). In the longer term, neither the organization, its customers, nor the CRB benefit by the use of softer classifications, as this risks the nonconformity being given a lower priority for corrective action.

The audit evidence should be documented and be sufficiently detailed, to enable the audited organization to find and confirm exactly what the auditor observed.

The next step the auditor will need to take is to identify and record the specific requirement that is not being met. Remember, a nonconformity is *non-fulfillment of a requirement*, so if the auditor cannot identify a requirement, then the auditor cannot raise a nonconformity.

Requirements can come from many sources; for example, they may be specified in ISO 9001: 2000, in the organization's management system (internal requirements), in applicable regulations, or by the organization's customer. Once the nonconformity

against a specific requirement is confirmed, this needs to be documented. The record may be something as simple as a reference to the standard and relevant clause.

(Note; ISO 9001 contains clauses that include more than one requirement. It is important that the auditor identifies and records the specific requirement relating to the nonconformity clearly, for example, by writing-out the exact text of the requirement from the standard that is applicable to the audit evidence. This may also apply to other sources of requirements.)

The final (and most important) part of documenting a nonconformity is the writing of a statement of nonconformity. **The statement of nonconformity drives the cause analysis, correction and corrective action by the organization,** so it needs to be precise.

The statement of nonconformity should:

- be self-explanatory and be related to the system issue
- be unambiguous, linguistically correct, and as concise as possible
- not be a restatement of the audit evidence, or be used in lieu of audit evidence.

To summarize, a well-documented nonconformity will have three parts:

- the audit evidence,
- the requirement, and
- the statement of the nonconformity.

If all three parts of the nonconformity are well documented, the auditee, or any other knowledgeable person, will be able to read and understand the nonconformity. This will also serve as a useful record for future reference.

In order to provide traceability, facilitate progress reviews, and evidence of completion of corrective actions, it is essential that nonconformities are recorded and documented in a systematic manner. A simple way of achieving this is through the use of a Nonconformity Report (NCR) form. Please see annex A below, for an example of such a form.

Annex A – Example of a Nonconformity Report (NCR) form

NCR #	**Client:**		**File No**	
Function/Area/Process:			**Site:**	
Std. and Clause No(s):				
Section 1- Details of non-conformity:				
Description				
Auditor :		Auditee representative acknowledgement:		Category:
Date:				
Section 2- Auditee Proposed Action Plan **(Attach separate sheet if required)**				
Root Cause analysis (how/why did this happen?):				
Correction (fix now) with completion dates:				
Corrective Action (to prevent recurrence) with completion dates:				
"Auditor" review and acceptance of Corrective Action Plan:				
Auditee representative:			Date:	
Section 3- Details of "Auditor" verification of Auditee implementation of action plan				
Section 4- NCR closed out by "Auditor" on (date):		**"Auditor" Team Leader name:**		

Date: 10 February 2005

ISO 9001 Auditing Practices Group

Guidance for reviewing and closing nonconformities :

Introduction

The value that can be provided to an organization can be enhanced or diminished by the review that an auditor conducts of the organization's response to a nonconformity, as well as by the "close-out" process that is applied. An auditor will add value by ensuring that the organization has satisfactorily addressed correction/ analysis of the cause, and corrective action, as this will increase the likelihood of the organization achieving customer satisfaction.

This document provides guidance to help auditors in the process of reviewing and closing nonconformities arising from audits.

Review of actions in response to a Nonconformity

Management system auditors are responsible for reviewing the response to nonconformity and verifying the effectiveness of actions taken.

There should be three parts to the response of an organization to nonconformity:

- correction,
- analysis of cause, and
- corrective action.

or

- analysis of cause,
- correction, and
- corrective action.

(Note; two different sequences are given as it may depend on the product type, or the situation of the nonconformity, as to which is the correct one to be followed. However, the three parts to resolving the nonconformity are the same in each case. For example, for software, it is inadvisable to implement a *correction* until the cause is known. Alternately, as a hardware example, if a "Low Brake-pad" warning light were to illuminate in a vehicle and you immediately implemented the *correction* of replacing the brake pads before examining if the sensor was faulty, you might fail to resolve the problem and would have wasted time and resources.)

The authoritative source for making the opening statement are some pertinent definitions in ISO 9000: 2000.

> **Nonconformity**: non-fulfillment of a requirement (ISO 9000:2000, clause 3.6.2)
>
> **Correction**: action to eliminate a detected nonconformity (ISO 9000:2000, clause 3.6.6)
>
> **Corrective action:** action to eliminate the cause of a detected nonconformity or other undesirable situation (ISO 9000: 2000, clause 3.6.5)

Both correction and corrective action should be expected when there is a detected nonconformity.

"Correction" is action to eliminate a detected nonconformity. For example, correction may involve replacing nonconforming product with conforming product or replacing an obsolete procedure with the current issue, etc.

The definition of "corrective action" is "*action to eliminate the cause of a detected nonconformity*." Corrective action cannot be taken without first making a determination of the cause of nonconformity. There are many methods and tools available to an organization for determining the cause of a nonconformity, from simple brainstorming to more complex, systematic problem solving techniques (e.g. root cause analysis, fish-bone diagrams, "five whys", etc). An auditor should be familiar with the appropriate use of these tools. The extent and effectiveness of the corrective actions depends upon identifying the true cause. In some cases this will assist an organization to identify and minimize similar nonconformities in another areas.

In reviewing the response of an organization to a nonconformity, the auditor should confirm that documentation and **objective evidence** for all three parts—correction/ analysis of the cause, and corrective action—are provided by the organization, and are appropriate, before accepting the response. Important elements to verify in the review process include:

- statements of actions; are they clear and concise ?
- descriptions of actions; are they thorough and do they accurately reference specific documents, procedures etc., as appropriate?
- the use of the past tense (was, has or have been, were), as an indicator that the actions taken have been completed.
- the date of completion of the corrective actions; past dates should be found that indicate that the actions have been taken (dates indicating future action are not good practice).
- evidence supporting the claim that a corrective action has been fully and effectively implemented and that the corrective action has been performed in the way that it was described.

Additionally, the auditor should verify that the organization has ensured that the corrective action taken does not itself create further problems relating to product quality or to implementation of the QMS.

It should be noted that both correction and corrective action are not always appropriate and that either correction or corrective action may be sufficient on their own. This may happen, for example, in cases in which it can be demonstrated that the nonconformity was absolutely accidental, and the probability of re-occurrence is very low.

Effective corrective action should prevent the recurrence of the nonconformity, by eliminating the cause. However, corrective action should not be confused with preventive action. The definition for preventive action is as follows:

> **Preventive action:** action to eliminate the cause of a **potential** nonconformity or other undesirable situation (ISO 9000:2000, clause 3.6.4)

It should be noted that preventive action, by the nature of its definition, is not applicable to already detected nonconformities. However, an analysis of the causes of detected nonconformities may identify potential nonconformities on a wider scale in other areas of the organization and provide input for preventive action.

Closing nonconformities

As nonconformities tend to be individual in their nature, a variety of methods or activities may be used to close them off. For example, some will require direct examination on site (which may require the need for additional site visits), while others may be closed-off remotely (by review of submitted documentary evidence).

Before deciding to agree to close-off a nonconformity, an Audit Team Leader (or the Auditor, in sole auditor situations) should review what the organization did in respect of correction/analysis of the cause, and the results it achieved through corrective action. The Audit Team Leader/Auditor needs to ensure that there is objective evidence (including supporting documentation) to demonstrate that the described corrective action has been fully implemented and is effective in preventing the nonconformity from re-occurring. Only once the situation is satisfactory, should the nonconformity be closed-off.

Date: 10 February 2005

ISO 9001 Auditing Practices Group Guidance on:

Auditing Internal Communications

1. Introduction.

An effective internal communication process contributes to the success of any organization's quality management system. Conversely, many problems that occur with an organization's quality management system can often be traced back to ***poor*** communication.

2. Requirements and Guidance

2.1 ISO 9001:2000 clause 5.5.3 states as follows:

> **"Internal communication**
> Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system."

This is one of a number requirements that have been introduced in ISO 9001:2000 where a definitive ("YES/NO") approach may not be adequate to evaluate the effective implementation of the internal communication process within an organization.

2.2 Other ISO 9001:2000 requirements regarding internal communication:

There are a number of other requirements in ISO 9001:2000 where top management has a responsibility to communicate with people in the organization with regard to:

- The quality policy and objectives
- The importance of meeting customer as well as statutory and regulatory requirements,
- The promotion of awareness of customer requirements throughout the organization.
- People's defined responsibilities and awareness of the relevance and importance of their activities, and how they contribute to the achievement of the quality objectives
- Where product requirements are changed, to ensure that relevant personnel are made aware of the changed requirements.

2.3 Guidance from ISO 9004:2000 (clause 5.5.3):

"The management of the organization should define and implement an effective and efficient process for communicating the quality policy, requirements, objectives and accomplishments. Providing such information can aid in the organization's performance improvement and directly involves its people in the achievement of

quality objectives. Management should actively encourage feedback and communication from people in the organization as a means of involving them."

It is important to note that this guidance from ISO 9004 is not auditable, but it does provide additional insights into the relevance of internal communication.

3. Verifying the effectiveness of internal communications

There are two main components of the requirements of ISO 9001:2000 clause 5.5.3 that have to be verified:

a) That appropriate communication processes have been ***established*** within the organization, including the:
   - Identification of the people between whom the communication is to occur;
   - information to be communicated;
   - means by which this is to be achieved;
   - method selected to monitor its effectiveness;
   - documentation and records necessary to verify it has occurred;
   - communication process is subject to continual improvement.

b) That the communication **is** taking place and **is related to the effectiveness of the quality management system**.

In searching for evidence of an effective communication processes the auditor may need to observe some or all of the following as appropriate to the organization that:

- top management, employees at all levels in the organization, contractors, generate, receive and respond to communications;
- the information to be communicated is clearly defined, appropriate and accurate to the purpose of the communication;
- the means used for communication is appropriate to the literacy and other skills of those expected to receive and act upon the information provided;
- monitoring takes place to ensure that the information communicated is acted upon and the desired outcome achieved;
- the procedures and records necessary to demonstrate that communication has occurred, is effective and subject to continual improvement are available.

Although there is no specific requirement for a documented procedure, depending on the size, complexity and culture of the organization it may be necessary to have one in order to ensure its effective implementation.

4. The auditors approach

Some or all of the following means of communicating information within the organization may be observed by the auditor:

- Management led communication in work areas
- Team briefings and other meetings, such as those for recognition of achievement
- Notice boards
- E-mail, intranet and web sites
- Company or in house magazine/newsletter
- Staff meetings

- Individual notices or letters

The auditor may be able to judge the effectiveness of the organization's internal communication processes by:

- Interviewing employees to determine awareness of policy, objectives and management system performance.
- Evaluating the causes of nonconformities and the organization's corrective action processes. Could the need for corrective action be linked/traced to poor internal communication processes?
- Evaluating the relevance and significant dates of displayed information. The information that is being communicated is of no value if it is out of date.
- Examining the feedback mechanisms within the organization, e.g. one-to-one interviews or reviews, employee surveys etc.
- Evaluating training and induction programs within the organization. These programs should contain information on how the quality management system operates.
- Viewing minutes of meetings containing items of internal communication.

5. Evaluation of the organization's compliance with ISO 9001:2000 requirements.

It is doubtful if an auditor can determine the effectiveness of the organization's internal communication processes during a single audit session or "time slot". It requires a more holistic approach throughout the entire audit, but need not be included as separate item in the audit plan. Audit teams should plan for a collaborative review of this issue.

Similarly it is doubtful if the effectiveness of the organization's internal communication processes can be determined solely from one source in the organization.

Compliance with the ISO 9001:2000 requirements should only be determined at the end of the audit, after evaluation of audit evidence (and after reaching consensus with other team members).

Date: 10 February 2005

ISO 9001 Auditing Practices Group Guidance on:

Auditing Preventive Action

1) Introduction

ISO 9000:2000 clause 3.6.4 defines preventive action as “action to eliminate the cause of a potential nonconformity or other undesirable potential situation”.

This can be considered as an action taken to prevent a nonconformity from happening. However, if there is no nonconformity to start with, and if the preventive action is effective, the status quo will be maintained. This raises the difficulty of auditing a process for which the desired output is to maintain the status quo.

There is often confusion about the differences between the terms i.e. correction, corrective action and preventive action (please refer to ISO 9000:2000 for their formal definitions), and also in relation to an organization's activities in respect of each of them.

Auditing an organization’s correction and corrective action processes is relatively straightforward, because the results and effectiveness of these processes are usually well defined (i.e. if the organization has already identified a nonconformity, it is relatively simple for an auditor to evaluate the process the organization used, or is planning to use, to correct it, and whether or not this will be effective in avoiding re-occurrence of the nonconformity); however, auditing preventive action processes is usually more complex.

2) Auditing Guidance

2.1) ISO 9001:2000 requires the organization to have a documented procedure for preventive action.

Note: The combination of corrective action and preventive action documented procedures into a single QMS document is acceptable, but is not recommended. If these are combined, then it is important for the auditor to verify that the organization understands clearly the difference between the intent of corrective and preventive actions.

2.2) The Standard requires this documented procedure to include:

a) **How the organization determines potential nonconformities and their causes**.

Typical examples include:

- Trend analysis for process and product characteristics (output from the data analysis process). A worsening trend might indicate that if no action is taken, a nonconformity could occur.
- Alarms to provide early warning of approaching "out-of-control" operating conditions.
- Monitoring of customer perception, by both formal or informal feedback systems.
- Analysis of trends in process capability, using statistical techniques.

- Ongoing failure mode and effect analysis for processes and products (this is a requirement of TS 16949, for the automotive industry, for example).
- Evaluation of nonconformities that have occurred in similar circumstances, but for other products, processes, or other parts of the organization, or even in other organizations.
- Through planning activities for both predictable situations (e.g. due to expansion, maintenance, or personnel changes – see also ISO 9001, Clause 5.4.2b)) and for unpredictable situations (e.g. naturally occurring problems such as hurricanes, earthquakes, floods etc.)
- ISO 9004:2000 clause 8.5.3 *Loss prevention* provides other examples (Note: this ISO 9004 guidance is not mandatory).

b) **An evaluation of the need for preventive action**.

Methods used in the evaluation could include:
- Risk analysis approaches
- Failure mode and effect analysis, as mentioned in (a) above.

(Note: neither of these specific approaches or methodologies are requirements of ISO 9001:2000.)

c) **How the organization determines what action is required, and how it is implemented**.

An auditor should look for evidence that:
- the organization has analyzed the causes of potential nonconformities (use of cause and effect diagrams and other quality tools may be appropriate for this).
- the required actions are deployed in all relevant parts of the organization, and in a timely manner
- there are clear definitions of the responsibilities for the identification, evaluation, implementation and review of preventive actions

d) **Records of the results of the actions taken**
- What records are kept?
- Are they appropriate, and are they a true reflection of the results?
- Are they being controlled in accordance with ISO 9001:2000 clause 4.2.4?

e) **A review of the preventive actions taken**
- Were the actions effective (i.e. was a nonconformity prevented from occurring and were there any additional benefits)?
- Is there a need to continue with the preventive actions the way they are?
- Should they be changed, or is it necessary to plan new actions?

2.3) There is often significant “philosophical” discussion between the auditor and the organization about where corrective action ends, and where preventive action begins. For example, if a nonconformity is detected in process “A”, are actions taken to avoid future nonconformities in processes “B”, “C” and “D” preventive actions, or simply within the scope of the corrective actions taken for process ”A”? The auditor should avoid being “side-tracked” by these discussions, and concentrate on whether or not the actions were effective. The “labeling” of the actions taken is of secondary importance!

Date: 30 July 2005

ISO 9001 Auditing Practices Group Guidance on:

Auditing service organizations

1. Introduction

Although ISO 9001:2000 is intended to apply to all kinds of organizations, regardless of type, size or product provided, there are a number of characteristics of service organizations that require specific attention during a third party audit. Consequently, this document aims to provide auditors with guidance on auditing the compliance of service organizations to the requirements of ISO 9001:2000. Particular emphasis is given to the requirements of clause 7.3 *Design and development*, clause 7.5.2 *Validation of processes for production and service provision* and clause 8.3 *Control of nonconforming product*.

2. Service Organizations

According to ISO 9000:2000, clause 3.4.2 *Product*:

> "Service is the result of at least one activity necessarily performed at the interface between the supplier and customer and is generally intangible. Provision of a service can involve, for example, the following:
>
> — an activity performed on a customer-supplied tangible product (e.g. automobile to be repaired);
>
> — an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return);
>
> — the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission);
>
> — the creation of ambience for the customer (e.g. in hotels and restaurants)."

Most organizations have an element of service in their product. This may range from almost 100% service (in the case of a law firm, for example), to a relatively small service component in the case of a manufacturing organization providing, for example, after-sales service.

3. Auditing Guidance

3.1 Design and development of the service

When considering the applicability or not of clause 7.3 of ISO 9001:2000 to a service organization, it is important to remember the definition of "Design and development", which, according to ISO 9000:2000 clause 3.4.4 is the "set of processes that transforms requirements into specified characteristics". Again, according to ISO 9000:2000 ***requirements*** are "needs and expectations that are stated, generally implied or obligatory", and ***characteristics*** of the service are distinguishing features that can include:

- sensory (e.g. related to smell, touch, taste, sight, hearing)

- behavioral (e.g. courtesy, honesty, veracity)
- temporal (e.g. punctuality, reliability, availability)
- ergonomic (e.g. physiological characteristic, or related to human safety)
- tangible (e.g. measurable characteristics; these may be either the characteristics of the physical means used to deliver the service, e.g. the maximum speed of an aircraft, or of the environment in which the service is provided, e.g. the interior temperature or facilities of an aircraft).

It is quite common for organizations to consider only the tangible component of their product when addressing the requirements of clause 7.3, forgetting that the design and development of the intangible product (the service itself) should be the main focus. Additionally, the organization will need to design how the service will be delivered to its customers.

If the organization proposes to justify the exclusion of design and development from its QMS, the auditor should make a careful assessment of the justifications in light of the above. The auditor should also examine whether the organization has an effective design and development process that sufficiently defines the characteristics of its service, and of its service delivery processes, that are needed to meet customer needs and expectations.

3.2 Validation of processes for production and service provision

In terms of the processes needed to realize the service, we can identify two types of service processes:

- those involving the customer in the realization of the service itself (real time delivery) and
- those in which the output is delivered to the customer after the realization of the process

Using the example of a hotel, the guest “check-in” and “check-out” processes would probably involve “real-time” delivery of the service, whilst the cleaning of the guest’s room would generally be “delivered” to the guest only after completion of the process (which could be subject to inspection and rework if necessary, to correct any nonconformities).

Similar processes can also be found in manufacturing organizations providing services related to their products, for example, the handling of claims and warranties; the repair of products by the organization's service units; or product maintenance activities performed at a clients' facilities.

Those processes that involve real time delivery, and are carried out directly at the organization/customer interface can rarely (if ever) have their output (“the service”) verified by subsequent monitoring or measurement before they are “delivered” to the customer. Therefore, such processes are indeed subject to validation according to the requirements of ISO 9001:2000, clause 7.5.2. This is also essential in order to ***prevent*** nonconformities from occurring.

In order to ensure adequate control over the quality of the service to be provided, the auditor should:
- understand the service characteristics, the service provision processes, and their acceptance criteria, as defined by the organization (this should be done during the Stage 1 audit)
- determine whether validation of "real-time" service provision processes (or any other process that requires validation) has been performed and if this has taken into account the associated risks;

- assess if the appropriate tools, training and empowerment have been provided to the personnel involved.

For many service industries, the service provided is instantaneous (i.e. via "real- time" processes), which does not readily allow for inspection before delivery of that service. Quality thinking says that the most cost-effective way of doing business is to apply the philosophy of “special processes” to ALL processes: the more the organization gets its processes right, the less the organization needs to worry about the outcome of their processes. Therefore it is very unlikely that this clause can be excluded.

3.3 Control of nonconforming product

In the cases of service processes directly involving the customer, “the control of nonconforming product” (clause 8.3) is the way the organization deals with nonconformities in the service provision until the appropriate corrective action is defined and implemented.

Where a nonconformity is identified, the auditor should examine:

- whether the personnel involved are sufficiently empowered with the authority to decide the disposition of the service, for example:
    - to immediately terminate the service
    - to replace the service provided
    - to offer an alternative
- the organization's customer claims and complaints processes
- any temporary corrections that are implemented to mitigate the effect of the nonconformity (e.g. refund, credit, upgrade, etc.)
- the identification, segregation and replacement of the relevant service equipment, service providers and environment.

This will enable the auditor to judge whether the control of such nonconforming product is effective.

Note: In such situations the quality management system should have provisions to capture data on the nonconformities and to feedback information, at the appropriate management level, for the effective definition and implementation of corrective actions.

For cases in which the output of the service is delivered after the realization of the process, “control of nonconforming product” may be based on usual monitoring and inspection techniques. Evidence will need to be sought of the adequacy and effective implementation of these techniques.

Date: 30 July 2005

ISO 9001 Auditing Practices Group Guidance on:

THIRD PARTY Auditor impartiality and conflict of interest

Impartiality and objectivity of auditors are basic prerequisites for an effective and consistent audit.

This paper illustrates good behavioural practices for the benefit of the auditors themselves and of the bodies in charge of assessing auditor behaviour, i.e. certification/registration bodies (CRBs) and accreditation bodies, (see also ISO/PAS 17001).

1. Scope

1.1 The overall aim of third-party certification is to give confidence to all parties that rely on certification. The main principles for inspiring confidence are independence, impartiality and competence both in action and appearance.

1.2 This paper only concerns itself with issues relating to the threats and safeguards to auditor independence and impartiality.

2. CRB commitment to impartiality

2.1 The organizational structure and procedures of the CRB employing the auditors should be able to demonstrate how the primary requirement of IMPARTIALITY is fulfilled.

2.2 The CRB should demonstrate, by means of policies, procedures and training how it deals with the pressures and other factors that can compromise or can reasonably be expected to compromise an auditor's objectivity and which may arise from a wide variety of activities, relationships, and other circumstances as well as from various personal qualities and characteristics of auditors that may be sources of bias.

3. Threats to auditor impartiality

3.1 Threats to auditor impartiality are sources of potential bias that may compromise, or may reasonably be expected to compromise, an auditor's ability to make unbiased audit observations and conclusions.
Because threats may, or may reasonably be expected to, compromise an auditor's ability to make unbiased audit observations and conclusions, CRBs should identify and analyse the effects of threats that are sources of potential bias.

3.2 Threats are posed by various types of activities, relationships, and other circumstances. In order to understand the nature of those threats and their potential impact on auditor impartiality, the CRB should identify the types of threats posed by specific activities, relationships or other circumstances. The following list provides examples of the types of threats that may create pressures and other factors that can lead to biased audit behaviour.

Although the list is not mutually exclusive or exhaustive, it illustrates the wide variety of types of threat that CRBs need to consider when analysing auditor independence and impartiality issues.

- Self-interest threats — threats that arise from auditors acting in their own interest. Self-interests include auditors' emotional, financial, or other personal interests. Auditors may favour, consciously or subconsciously, those self-interests over their interest in performing a management system audit. For example, CRB relationships with clients create a financial self-interest because the clients pay the CRB's fees. Auditors also have a financial self-interest if they own shares in an auditee and may have an emotional or financial self-interest if an employment relationship exists between auditor's family members and an auditee.
- Self-review threats — threats that arise from auditors reviewing the work done by themselves or by their colleagues. It may be more difficult to evaluate without bias the work of one's own organization than the work of someone else or of some other organization. Therefore, a self-review threat may arise when auditors review judgments and decisions they, or others in their organization, have made.
- Familiarity (or trust) threats — threats that arise from auditors being influenced by a close relationship with an auditee. Such a threat is present if auditors are not sufficiently sceptical of an auditee's assertions and, as a result, too readily accepts an auditee's viewpoint because of their familiarity with or trust in the auditee. For example, a familiarity threat may arise when an auditor has a particularly close or long-standing personal or professional relationship with an auditee.
- Intimidation threats — threats that arise from auditors being, or believing that they are being, openly or secretly coerced by auditees or by other interested parties. Such a threat may arise, for example, if an auditor or CRB is threatened with replacement over a disagreement with an auditee's application of a specific requirement of the normative document being used as the reference for the audit.
- Advocacy threats (e.g. a body or its personnel acting in support of, or in opposition to, a given auditee, which is at the same time its customer, in the resolution of a dispute or litigation);
- Competition threats (e.g. between assessed auditee and a contracted technical assessor).

4 Safeguards to auditor impartiality

4.1 The CRB should have in place safeguards that mitigate or eliminate threats to auditor impartiality. Safeguards may include prohibitions, restrictions, disclosures, policies, procedures, practices, standards, rules, institutional arrangements, and environmental conditions. These should be regularly reviewed to ensure their continuing applicability.

NOTE 1 Safeguards exist in the environment in which audits are performed or can be mandated by independent decision makers in response to threats posed by various activities, relationships, and other circumstances. One way in which safeguards can be described is by where they reside.

4.2 Examples of safeguards that exist in the environment in which audits are performed include:

- the value CRBs and individual auditors place on their reputations;
- accreditation programmes for CRBs that assess organization-wide compliance with professional standards and regulatory requirements regarding impartiality;
- general oversight by CRBs' committees and governance structures (for example, boards of directors) concerning compliance with impartiality criteria;

- other aspects of corporate governance, including the CRB's culture that supports the certification process and auditor impartiality;
- rules, standards, and codes of professional conduct governing auditors' behaviour;
- the raising of sanctions, and the possibility of such actions, by accreditation bodies/IAF and others; and
- the legal liability faced by CRBs.

4.3 Examples of safeguards that exist within certification bodies as part of a CRB's management system include:

- maintaining a culture in the CRB that stresses the expectation that auditors will act in the wider interest and the importance of good audits and auditor impartiality;
- maintaining a professional environment and culture in the CRB that supports behaviour of all personnel that is consistent with auditor impartiality;
- management systems that include policies, procedures, and practices directly related to maintaining auditor impartiality;
- other policies, procedures, and practices, such as those concerning the rotation of staff, internal audit, and requirements for internal consultation on technical issues; and
- personnel hiring, training, promotion, retention, and reward policies, procedures, and practices that emphasize the importance of auditor impartiality, the potential threats posed by various circumstances that auditors in the CRB may face, and the need for auditors to evaluate their impartiality with respect to a specific client after considering safeguards in place to mitigate or eliminate those threats.

4.4 Another way of describing safeguards is by their nature. Examples include:
- safeguards that are preventive — for example, an induction programme for newly hired auditors that emphasizes the importance of impartiality;
- safeguards that relate to threats arising in specific circumstances — for example, prohibitions against certain employment relationships between auditors' family members and the CRB's clients and;
- safeguards whose effects are to deter violations of other safeguards by punishing violators — for example, a zero tolerance policy enabling accreditation bodies to immediately suspend or withdraw accreditation.

4.5 An alternate way in which safeguards can be described is by the extent to which they restrict activities or relationships that are considered threats to auditor impartiality, such as prohibiting auditors from providing consultancy to the clients they are auditing.

4.6 In assessing the impartiality of its auditors a CRB should consider:

- the pressures and other factors that might result in, or might reasonably be expected to result in, biased audit behaviour — here described as threats to auditor impartiality;
- the controls that may reduce or eliminate the effects of those pressures and other factors — here described as safeguards to auditor impartiality;
- the significance of those pressures and other factors and the effectiveness of those controls; and
- the likelihood that pressures and other factors, after considering the effectiveness of controls, will reach a level where they compromise, or may reasonably be expected to compromise, an auditor's ability to maintain an unbiased audit behaviour.

5. Assessing the level of impartiality risk

CRBs should assess the level of impartiality risk by considering the types and significance of threats to auditor impartiality and the types and effectiveness of safeguards. This basic

principle describes a process by which CRBs should identify and assess the level of impartiality risk that arises from various activities, relationships, or other circumstances.

NOTE 1 The level of impartiality risk can be expressed as a point on a continuum that ranges from “no risk” to “maximum risk.” One way to describe those endpoints, the segments of the impartiality risk continuum that fall between those endpoints, and the likelihood of compromised objectivity to which the endpoints and segments correspond, is as follows:

Table 1 — Level of impartiality risk

No risk	**Remote risk**	**Some risk**	**High risk**	**Maximum risk**
Compromised objectivity is virtually impossible	Compromised objectivity is very unlikely	Compromised objectivity is possible	Compromised objectivity is probable	Compromised objectivity is virtually certain

Increasing likelihood of compromised objectivity →

NOTE 2 Although it cannot be measured precisely, the level of risk for any specific activity, relationship, or other circumstance that may pose a threat to auditor impartiality can be described as being in one of the segments, or at one of the endpoints, on the impartiality risk continuum.

6. Determining the acceptability of the level of impartiality risk

6.1 CRBs should determine whether the level of impartiality risk is at an acceptable position on the impartiality risk continuum. CRBs should evaluate the acceptability of the level of impartiality risk that arises from specific activities, relationships, and other circumstances. That evaluation requires them to judge whether safeguards eliminate or adequately mitigate threats to auditor impartiality posed by those activities, relationships, or other circumstances. If they do not, CRBs should decide which additional safeguard (including prohibition) or combination of safeguards would reduce the risk, and the corresponding likelihood of compromised objectivity, to an acceptably low level.

6.2 Given certain factors in the environment in which audits take place — for example, that the auditor is paid by the auditee — the impartiality risk cannot be completely eliminated and, therefore, CRBs always accept some risk that auditors’ objectivity will be compromised. Nevertheless, in the presence of threats to auditor impartiality, CRBs should consider only a very low level of risk to be acceptable. Only such a small likelihood of compromised objectivity is consistent with both the definition and the goal of auditor impartiality.

6.3 Some threats to auditor impartiality may affect only certain individuals or groups within a CRB, and the significance of some threats may be different for different individuals or groups. To ensure that the risk is at an acceptably low level, CRBs should identify the individuals or groups affected by threats to impartiality and the significance of those threats. Different types of safeguards may be appropriate for different individuals and groups depending on their roles in the audit.

6.4 CRBs should ensure that the benefits resulting from reducing the impartiality risk by imposing additional safeguards exceed the costs of those safeguards. Although benefits and costs are often difficult to identify and quantify, CRBs should consider them when they make decisions about auditor impartiality issues.

NOTE Various parties bear a variety of costs in maintaining auditor impartiality. Some of those costs relate directly to developing, maintaining, and enforcing safeguards, including the costs of a CRB's impartiality-related quality controls and costs related to the systems of

accreditation and self-regulation of auditor impartiality. Other, indirect, costs of maintaining auditor impartiality, sometimes called "second-order effects" or "unintended consequences", also may exist. Those costs relate to possible reductions in audit quality or other negative outcomes that may result from safeguards that prohibit or restrict auditors' activities and relationships. For example, restrictions on auditor consultancy/training activities may reduce the attractiveness of CRBs as employers and thereby lead to reduced audit quality. The direct and indirect costs of maintaining auditor impartiality may be affected by many variables, including the number of individuals in an organization who will be affected by a safeguard. Because the impartiality of auditors is important not only in its own right but also in helping ensure that broad public interest objectives are met, CRBs should consider second-order effects or unintended consequences that go beyond the direct impact of their decisions on the impartiality of auditors.

7. Organizational and structural issues

7.1 In addition to the aspects outlined above, auditor impartiality needs to be further protected by placing it within an organizational structure, which will guarantee that the safeguards required are implemented. The organizational structure should be such that the CRB can demonstrate its impartiality to an informed and disinterested third party.

7.2 The structure and organization of the CRB chosen to meet these objectives should be transparent and support the development and the application of the processes necessary to meet the above objectives. These processes should include:

- understanding the needs and expectations of customers and other stakeholders;
- establishing the policy and objectives of the organization;
- determining the processes and responsibilities necessary to attain the objectives;
- determining and providing the infrastructure and resources necessary to attain the objectives;
- establishing and applying methods to determine the efficiency and effectiveness of each process;
- the identification of potential conflict of interest at the level of both the organization and the individual, and the means of identifying it and dealing with it;
- determining means of preventing nonconformities and eliminating their causes; and
- establishing and applying a process for continual improvement of the above processes.

Note: While the guidance in this paper has been presented with a focus on CRB auditors, similar considerations may (with due adaptation) be applied to accreditation body auditors.

Date: 30 July 2005

ISO 9001 Auditing Practices Group Guidance on:

Auditing the effectiveness of the internal audit

1. Introduction

Organizations seeking a suitable, adequate, and effective quality management system need to conduct internal audits, to ensure that the QMS functions as intended, and that it identifies weak links in the system as well as potential opportunities for improvement. The internal audit acts as a feedback mechanism for the top management; it can give top management, and other interested parties, assurance that the system meets the requirements of ISO 9001:2000. How the internal audit process is managed is a key factor to ensuring the effectiveness of a quality management system.—

2. Requirements and Guidance

2.1 ISO 9001:2000 clause 8.2.2 states as follows:

8.2.2 Internal audit

> "An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits"

This requirement is intended to focus the internal audit programme on those processes and areas where past history indicates that problems have occurred, or where problems are likely to be ongoing, and/or are likely to occur (because of the nature of the processes themselves). These problems may result from issues such as human factors, process capability, measurement sensitivity, changing customer requirements, changes in the work environment, etc.

The processes with high levels of risk of deficiencies or non conformities should have priority in the internal audit programme.

Special attention should be given to processes where the high level of risk is influenced by factors such as:
- severe consequences of failure on process capability;
- customer dissatisfaction;
- non compliance with product (or process) statutory and regulatory requirements.

2.2 ISO 9004:2000 Clause 8.2.1.3

"Top management should ensure the establishment of an effective and efficient internal audit process to assess the strengths and weaknesses of the quality management system. The internal audit process acts as a management tool for independent assessment of any designated process or activity. The internal audit process provides an independent tool for use in obtaining objective evidence that

the existing requirements are fulfilled, since the internal audit evaluates the effectiveness and efficiency of the organization".

This guidance from ISO 9004 stresses the need for the efficient use of resources when conducting internal audits. (Note, this ISO 9004 guidance is not an auditable requirement for an ISO 9001 assessment).

3. Audit Guidance

When third party auditors examine internal audit processes, they should evaluate issues such as:

- the competencies that are needed for and applied to the audit,
- the risk analysis performed by the organization (if any) in planning internal audits,
- the degree of management involvement in the internal audit process,
- the guidance provided by ISO 19011 (but note that ISO 9001:2000 does not *require* the organization to use ISO 19011), and
- the way the outcome of the internal audit process is used by the organization to evaluate the effectiveness of its QMS and to identify opportunities for improvements.

A third party auditor needs to:

a) evaluate the organization's approach to identifying critical areas as well as other parameters;

For example, has the organization identified:

- its processes that are critical to product quality,
- its complex processes, or those that need special attention
- its processes that need to be validated
- its processes that need personnel to be qualified
- its processes that need close monitoring of process parameters
- its monitoring and measuring activities that require frequent calibration and/or verification;
- its activities and processes that occur across multiple locations and/or which are labour intensive etc.
- Processes where problems have occurred or are in risk
- and established process performance indicators that define effectiveness and efficiency measures, and do these measures align with the organization's overall goals and objectives.?

Does the organization uses such information when establishing the audit frequency of such processes and activities ?

b) evaluate the competence of the organization's internal auditors and audit teams;

There should be evidence that the organization:

- has identified the competence requirements for its internal auditors,
- has provided appropriate training
- has in place a process for monitoring the performance of its internal auditors and audit teams
- includes personnel on its audit teams that have appropriate sector specific knowledge (so that they are able to identify where the likelihood that a deviation in a particular process or activity could lead to a significant consequence for product quality)

An assessment should also be made of whether the internal auditors understand the inherent risk to the reliance that can be placed on the outcome of the audit process, if they:

- fail to consider something which is material to the outcome of the audit,
- select an inappropriate sampling regime,
- weight the evidence collected inappropriately, or
- deviate from the audit plan and internal audit procedures.

c) evaluate the planning of audits;

The organisation should be able to maximize the use of available resources during the conduct of internal audit activities. This can be facilitated by the adoption of a risk based approach to the planning of internal audits.

It should be ascertained whether the organization (through its internal audit process) has considered the use of a risk based approach in developing the internal audit plan, in order to ensure the effective and efficient use of resources, This should also ensure that the inherent risks of audit failure in the audit process, and to audit outcomes, are minimised.

The organization should have a process for utilizing past audit results in the planning of future internal audits.

d) look for evidence that the organization has implemented an effective internal audit programme.

By taking the above factors into account, and by examining whether the internal audit process is leading to any tangible improvements to the QMS, the 3rd party auditor should be able to form a judgement on whether the organization has implemented an effective internal audit programme and if the outcome of internal audits provides evidence for analysis of the effectiveness of the QMS.

Date: 25 August 2005

ISO 9001 Auditing Practices Group Guidance on:

Auditing Electronic-Based Management Systems (EBMS)

1. Introduction

The growing dependency of organizations on electronic media for the operation and control of their management systems requires certification/ registration bodies and their auditors to look at new approaches to ensuring that audits will be effective and efficient. They will need to redefine the way processes and related documents (including records) are evaluated to verify conformance with the audit criteria.

This paper has been developed to give general guidelines for the realization of audits of management systems that are either fully electronic-based or have a high degree of documentation in electronic media. It also provides guidelines for certification / registration bodies and auditors to consider as a complement to the normal planning and preparation activities that should occur prior to an audit.

This paper focuses on those requirements of ISO 9001 where there is the possibility of use of electronic documents, records etc., and also where access to such documents/records may be controlled by electronic systems.

This paper is intended for management system auditors who have a broad and varied range of practical experience with regard to electronic-based management systems (EBMS) – i.e. management systems that are dependent on electronic documents, data and software applications for their normal operation. However, it is written in a style that will also allow it to be used by those who only have limited experience of computers and EBMS.

Whether it is a third-party certification body, accreditation body or internal audit function, the organization carrying out the audit ("the auditing organization") is responsible for ensuring the effectiveness of the audit process for the EBMS. This paper utilizes the guidance provided in ISO 19011, and suggests approaches that may be utilized by auditors of ISO 9001, and other management system standards, in order to verify conformance to the referenced standard. Auditors and auditing organizations should make the adjustments necessary to ensure a suitable approach as they perform the audit process steps indicated in ISO 19011.

It should be noted that proficiency in the auditing of EBMS should not be viewed as an excuse to reduce audit durations, but as a means of optimizing the effectiveness and efficiency of the audit.

It is not the intention of this paper to provide guidelines for auditing controls associated with information security for EBMS. Those interested in further controls associated with information security are directed to ISO/IEC 17799 which is a comprehensive standard for these matters.

2. Audit Initiation and Planning

During the audit initiation phase (the Stage 1 audit) the auditing organization should determine the structure of the organization to be audited, and the degree to which its management system is electronically-based. A multi-site organization with a centralized EBMS, or a "virtual" organization, will require different auditing plans and methods to a single site and/or physical organization.

The auditing organization and the auditee should agree on how the auditors will access and use the EBMS. This may involve consideration of:

- Allowing the members of the audit team an opportunity to familiarize themselves with the auditee's EBMS (including the scheduling of sufficient time within the audit plan for such an orientation)
- The auditee's policies for the use of its Information Technology infrastructure
- Instructions for accessing, and the necessary security clearances to access, pertinent organizational documents and records
- Safeguards and processes to ensure that the auditors protect the confidentiality of electronic documents and records during, and subsequent to, the audit.

The auditing organization should ensure that there is sufficient competence within its selected audit team to carryout an effective assessment of the EBMS.

3. Document Review

Depending on whether or not the auditee has the ability to make its documentation available through a web-based application or through e-mail transmission, the auditing organization may conduct part or all of the document review off-site; either on-line or by downloading electronic documentation submitted by e-mail.

Depending on technical and security factors, it may be not be feasible to conduct a full review of an organization's EBMS on-line or via e-mail transmission of relevant documents, prior to arriving on site. In such instances, audit preparation activities requiring a review of electronic documents would need to occur at the facilities of the auditee during the Stage 1 audit.

4. On-Site Realization Activities

The audit approach for electronic-based management systems will depend largely upon how much of the evidence required for determining conformance is in the form of electronic records.

During on-site realization activities, the auditor's trail should typically include the physical location of the process being audited. However, with an EBMS the time needed to confirm the evidence for determining whether or not requirements are being met, may be dedicated at a computer workstation which may or not be located near the actual process.

When the computer workstations are in remote areas that are not accessible at the location of the physical process, the actual auditing time at the physical location of the process may be reduced. However, the overall assessment time may not necessarily need to be reduced, given that electronic evidence review may occur before and/or after confirming the existence of the physical process.

In the case where the associated computer workstation is remotely placed, special consideration should be given to the time required for traveling to and from the physical location of the process.

When the process is dependent on human intervention, the auditor should evaluate the methods employed for interaction between the physical process and electronic media to ensure the accuracy of the associated information.

5. Auditing the Control of Electronic Documents

Electronic documents that establish management system policies and procedures can be in a variety of file formats depending on the software applications that are utilized by the organization to generate the documents. Electronic file formats include, Text, HTML, PDF, etc. Spreadsheets and databases formats are also considered to be electronic "documents" subject to the control elements of the management system to being audited.

Given the relative ease with which users can now create electronic spreadsheets and other electronic documents, auditors should ensure that policies governing the controls that apply to management system documentation in-general are also employed for electronic documents through appropriate procedures.

Organizations need to employ suitable and effective methods within the electronic environment for ensuring the adequate review, approval, publication and distribution of its management system documentation. These should be consistent with the methods for the development and modification of electronic documents.

In many cases document control measures may also be standard features of software applications used for their creation. Therefore auditors should understand these application-specific controls to the degree that these are utilized as a basis for conformance to the applicable management system standard.

Given the increased capacity to modify, update, reformat and otherwise improve documents within an electronic-based management system, auditors should pay particular attention to control elements such as document identification and document revision level.

As electronic media facilitates an increased rate of document modifications, auditors should verify that the controls being employed for the management of obsolete documents are considered within the organizations' document control policies and procedures.

Auditors should verify that EBMS documentation exists to provide orientation to users with regard to the functional and control aspects associated with electronic documents. Additionally, "Point-of-use" requirements associated with the applicable management system standards will typically be addressed in part by the organization's document access policies. Auditors should understand the organization's policies and procedures regarding user privileges as these become important factors for properly realizing the organization's processes.

External electronic communication with suppliers, customers and other interested parties may involve the exchange of documents. Given that these external documents may contain key parameters that specify the functioning of the organization's processes, auditors should verify the degree to which these documents are formally introduced and controlled within the electronic-based management system.

6. Auditing the Control of Electronic Records

Electronic records consist of the process output data combined with the electronic formats that house the data. These electronic formats range from simple spreadsheet documents to more complex database applications.

Auditors should be aware that the control elements that organizations establish for electronic forms are not necessarily the same as that which apply to electronic records. For example, with respect to “Identification”, in the case of electronic forms, the term refers to the nomenclature of the electronic form itself. When “Identification” is considered in the case of an electronic record, this refers to the unique use of the electronic form for a given data set.

Auditors should review the methods employed by the organization for capturing data, in order to ensure that data entry activities provide sufficient confidence in their accuracy.

When evaluating the organizations controls with regard to storage of records, auditors should verify if organizations have an understanding of their storage capacity versus:

- the rate of record generation,
- record retention policies and associated timeframes,
- the rate of record disposal,

as these factors may impact the proper functioning of the EMBS.

Given that the knowledge-base and the performance of the organization may be almost entirely in electronic records, Auditors should review the organizations approaches for securing the information contained in electronic means. For more information on Information Security see ISO / IEC 17799.

7. Organizational Resources

As organizations migrate to using an EMBS, the IT function’s role becomes vital. Auditors should verify if the organization has dedicated appropriate IT resources (including infrastructure) to ensure that EBMS operates continually and effectively.

Auditors should also verify if the organization has appropriately defined the level of interaction, support and involvement of IT personnel in matters associated with the establishment, documentation, implementation and maintenance of the EBMS.

As part of the verification of assignment of appropriate resources, Auditors should evaluate how the organization addresses the competence required of personnel to operate hardware and software to run the EBMS.

During establishment of an EBMS, it is customary that parallel (hardcopy and electronic) systems are in-place for a period of time to allow users to adapt. In these cases the auditor should verify the organization's approaches for ensuring that the EBMS is actually being assimilated and utilized by the organization’s personnel.

The complexity of organizations IT infrastructures will vary, depending on the nature and complexity of the business. Auditors should verify an organization's system maintenance policies and procedures for its IT platform. Also, auditors should verify how the organization addresses system downtime incidents, as these will impact the normal functioning of the EBMS. Auditors should evaluate whether or not the organization has

formal backup systems, and whether or not these are periodically reviewed and tested for adequacy.

In relation to software, the auditors should verify the controls established for internal software, external software, software licensing, and software updates. Since software can be considered to be a dynamic electronic document, the guidelines provided above for the auditing of documents would also be applicable to it.

To the extent that the organizations uses software for its EBMS, auditors should review the functionality of the applications and their relationship to management system elements defined in the applicable criteria.

As environmental factors may impact the functioning of an IT platform, organizations should take measures to protect them against such factors. This may range from the need for adequate facilities or housings through to the need for uninterruptible power supplies (UPS). Auditors should evaluate if the organization's controls take into account aspects such as facility maintenance, temperature, humidity, etc, to the extent that these bear upon the operation of the EBMS.

8. Internal and External Electronic Communication

As the options available for, and ease of use of electronic communication increases, organizations should ensure that the documented management system addresses these means, as necessary, to ensure consistency in their use for satisfying the requirements of their EBMS and the applicable management system standard.

When Intranets, Email, and Instant Messaging are utilized for satisfying the requirements of the EBMS, auditors should verify that policies and procedures address the circumstances under which these means would be employed. Additionally, if the results of internal electronic communication are to be used to satisfy the audit criteria, then auditors should verify that policies and procedures for the control of records are being applied.

When the organization relies on its IT infrastructure for electronic communications with its customers (e.g. for e-commerce), suppliers (e-procurement), external sites and other interested parties, the auditor should verify that the methodology, policies and procedures for these communications and associated transactions are formally addressed within the EBMS.

9. Multi-Site Management Systems

Organizations that operate through multiple sites (or from a central location to satellite sites) usually maintain communications and share policies, procedures and process data with their various locations via electronic means, such as the internet, extranets, e-mail and instant messaging.

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When the IT platform and its associated software applications are used to share information that is pertinent to the Audit Criteria, auditors should understand the different networking means employed by the organization to the extent that it is necessary for ascertaining if the EBMS meets with the audit criteria

Auditors should verify whether the controls over a multi-site management system are appropriately addressed and established within the organization's policies and procedures.

10. Auditor Competence

The reliability of the audit process for EBMS will depend on the ability of auditors to understand the trends in Information Technology as organizations rely increasingly on software for monitoring and controlling their operations.

Auditing Organizations should take the necessary measures, including the provision of training, to address the general and individual needs of their auditor base with regard to:

- General trends in Information Technology that may impact the operation of management systems

- Audit-specific considerations for each audit assignment that is undertaken

As the innovations in the IT sector are relatively rapid as compared to changes in Audit Criteria, auditors and auditing organizations are challenged with the need to have a practical understanding of the associated trends and how they may be applicable and utilized within an EBMS.

In light of the innovations that influence the functioning of an EBMS, Auditing Organizations should determine if the experience needed in order to be effective for a given audit is possessed by the audit team itself or whether the assistance of a technical expert would required.

Date: 12 December 2005

ISO 9001 Auditing Practices Group Guidance on:

AUDITING THE MANAGEMENT OF RESOURCES

Auditors should verify that the resources needed to implement, maintain and improve the quality management system are adequately managed. This means that appropriate resources are to be identified, planned, made available, used, monitored and changed as necessary by the organization.

It is recommended that the management of resources is not audited in isolation. Irrespective of the way the organization is structured and identifies its processes, auditors should be able to verify the adequacy and effective management of the resources to achieve planned results. It is important for auditors to verify whether the organization has evaluated past and present performance (e.g. using cost-benefit analysis, risk assessment) when deciding what resources are to be allocated.

Management of resources can be evaluated by interviews with top management and other responsible personnel to check that suitable processes are in place. This needs, however, to be supported by objective evidence collected throughout the audit.

Evidence can be obtained at different stages of the audit – reviewing inputs, process performance and outputs. This has to be carried out when auditing all the processes and related system and process documentation, such as:-

- management commitment and responsibilities;
- management review process;
- product realization processes including the control of nonconforming products, corrective and preventive actions and continual improvement.

Auditors should avoid making subjective judgements on the adequacy of the resources allocated by the organization and should limit their role to the evaluation of the effectiveness of the resource management process.

Auditors should verify that the human resources, infrastructure (energy, water, facilities and equipment maintenance, communications, information technology, etc.), and the work environment (temperature, lighting, vibration, noise, etc.) have been provided and maintained in a way consistent with the quality policy and objectives as well as contributing to conformity to product requirements.

If it is found that effective management of resources has not been taken into consideration by the organization which may result in not satisfying product related requirements, this should be treated as a nonconformity, the magnitude of which should be related to the associated risk.

Date: 12 December 2005

ISO 9001 Auditing Practices Group
Draft Guidance on:

Auditing Customer Communications

1. Introduction.

An effective customer communication process contributes to the success of any organization's quality management system and ultimately to the success of the organization itself. Conversely, many problems that an organization experiences with its customers can often be traced back to *poor* communication.

2. Requirements and Guidance

2.1 ISO 9001:2000 clause 7.2.3 states as follows:

"Customer communication"
The organization shall determine and implement effective arrangements for communicating with customers in relation to
a) product information,
b) enquiries, contracts or order handling, including amendments, and
c) customer feedback, including customer complaints.

2.2 An APG paper on auditing customer feedback and customer complaint processes has been published.

2.3 Other ISO 9001:2000 requirements regarding customer communication:
There are a number of other requirements in ISO 9001:2000 where reference is made directly, or indirectly, to customer communication.

- Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (clause 5.2)
- The organization's review of the requirements related to the product conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders); (clause 7.2.2).
- Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance (clause 7.2.2); the organization needs to have a system in place to obtain those requirements.
- Authorizing the use of non conforming product by release or acceptance under concession by a relevant authority and, where applicable, by the customer (clause 8.3b)).

2.4 Guidance from ISO 9004:2000 (clause 7.2):

"**Processes related to interested parties**
Management should ensure that the organization has defined mutually acceptable processes for communicating effectively and efficiently with its customers and other interested parties. The organization should implement and maintain such

processes to ensure adequate understanding of the needs and expectations of its interested parties, and for translation into requirements for the organization……"

3. Verifying the effectiveness of customer communications

Verifying the effectiveness of customer communication is therefore a critical component for achieving customer satisfaction. Although there is no specific requirement in ISO 9001:2000 for a documented procedure, depending on the size, complexity and culture of the organization it may be necessary to have one in order to ensure effective implementation of the customer communication process.

ISO 9000 defines the term "customer" as the recipient of the product. It further gives examples of customers including the "end user".

Many organizations sell their products / services through dealers and retailers and may not be receiving orders directly from the end users. It is important for the auditor to verify how the organization communicates about the quality of its product / service to the end users and also the mechanism for obtaining a feedback (besides complaints) from the end users. It should be recognized that the needs of the dealers / retailers may at times be different from those of the end users.

4. The auditor's approach

4.1 Customer communication falls in three general categories:

- An organization's general communication to existing or potential customers – such as advertisements or marketing information,
- Specific information relating to a customer enquiry, requirement or order, and
- Communication in response on customer feedback and complaints

4.2 Some or all of the following means of an organization's general customer communication may be observed by the auditor:

Product information, which includes

- advertising material
- web sites
- product catalogues

Where the organization receives orders from dealers and not the end users, the auditor should establish that the product information available to the end users (pamphlets, brochures, web sites etc) describes the product / service adequately and accurately. The auditor should also try to establish how the customer needs have been identified and product specifications arrived at.

4.3 The auditor would verify the product information to confirm that it is readily available to customers or potential customers and provides information that is up-to-date and accurate. The auditor could also query, for example, how often advertising material, web sites and product catalogues are reviewed to reflect the organizations current product offerings and services and what measures are taken if a particular product is modified, discontinued or no longer available.

4.4 Some or all of the following means of an organization's specific customer communication may be observed by the auditor:

Enquiries, contracts or order handling, including amendments

- quotations
- order forms
- confirmation of order
- amendment to order
- delivery documentation
- invoices
- credit notes
- e-mail & general correspondence
- visit reports or notes to/from customer

Customer feedback and complaints management process

- Letters in response to complaints
- Acknowledgments

4.5 There are also further instances where the auditor will experience the organization's communication with the customer:

- During the ordering process where the customer provides no documented statement of requirement, the organization needs to have a system in place to obtain or confirm these customer requirements before the organization accepts the order.

- During the design/development process there may be considerable communication between the organization and the customer.

- During the process of authorizing the use of non conforming product by release or acceptance under concession by a relevant authority and, where applicable, by the customer

4.6 The auditor would use normal trace methods to verify compliance with the customer communications requirements of ISO 9001 and whether the organization communicated effectively with the customer in the execution of the enquiry, contract or order.

Date: 8 December 2006

ISO 9001 Auditing Practices Group Guidance on:

Auditing the Design and Development Process

1. Introduction

The objective of auditing the design and development process is to determine whether it is managed and controlled to enable products to meet their intended use and specified requirements.

It is necessary to note that for service organizations, the approach to design and development may be different from "traditional" manufacturing organizations (see the guidance document on Auditing Service Organizations).

Before discussing in detail the way in which the design and development process should be audited it is vital for the auditor to understand what is meant by the phrase "Design and development". By misunderstanding this concept, many organizations have wrongly excluded this process from their quality management system.

ISO 9001:2000 clause 7.3 refers only to design and development of **products and services**. In some organizations it can be beneficial, but not required, to apply the same methodology to design and development of **processes**.

Product design and development is the set of processes for transforming requirements for the product (for example specifications, statutory requirements and specific or implied customer requirements) into specified product characteristics ("distinguishing features of the product"). ISO 9000:2005 Clause 3.4.1 gives the following examples of product characteristics:

- physical (e.g. mechanical, electrical, chemical or biological characteristics);
- sensory (e.g. related to smell, touch, taste, sight, hearing);
- behavioral (e.g. courtesy, honesty, veracity);
- temporal (e.g. punctuality, reliability, availability);
- ergonomic (e.g. physiological characteristic, or related to human safety);
- functional (e.g. maximum speed of an aircraft).

In order for the auditor to determine if the organization is in fact involved in design and development, auditors need to establish who is responsible for defining the characteristics of the product or service together with how and when this is carried out.

(Note:- This may apply to original design or ongoing design changes)

Generally, the design and development process consists of the stages shown in Figure 1 below. Each stage has specific deliverables that cover both the commercial and technical aspects of design and development of a product. In some cases, organisations might be able to justify the exclusion of certain sub-clauses or individual requirements from their

QMS, without necessarily excluding the entire clause. For an organisation with a long established and well validated product design, for example, the organisation might only need to ensure that design changes are managed in accordance with the requirements of clause 7.3. Auditors should verify that any exclusions are valid.

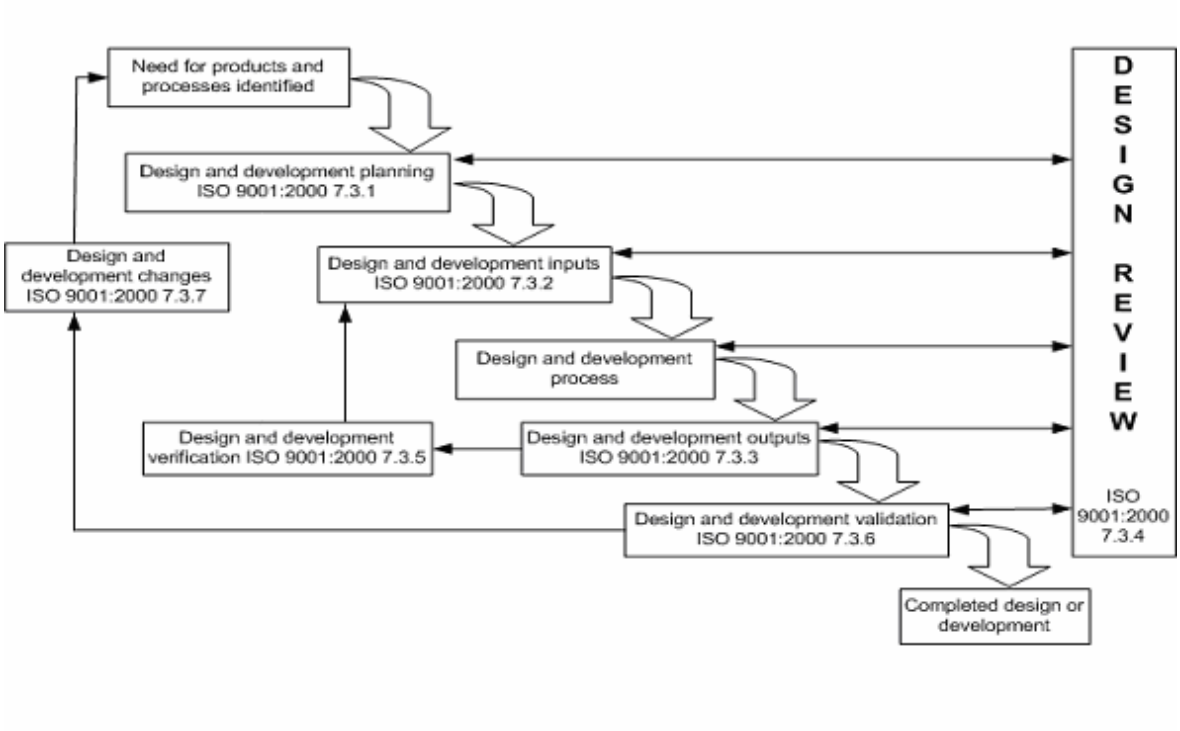

Figure 1 – Outline of the Design and Development Process

Auditors should establish what design and development projects have been, and are currently being, undertaken. Auditors should select a sufficient number of projects to be able to audit all stages of the design process.

Guidance for auditing the various stages of the design and development process is given below but it should be noted that it might not be possible to audit all stages for all the projects selected.

2. Auditing the need for design and development

The need for design and development is generated from a number of sources including:-

- the organization's strategic planning;
- market intelligence and research;
- service reports;
- customer feedback and demand;
- new or changed statutory and regulatory requirements;
- process changes;
- new technology;
- suppliers.

Auditors should evaluate whether organizations have in place, and perform, activities for the review of such needs. Whilst it is not a requirement of the standard it is useful to review how the decision to proceed with design and development is taken, i.e. have risks and cost implications been considered and have all relevant functions (internal or external) been consulted.

3. Auditing design and development planning

The following issues should be considered when auditing the planning function:

- what is the overall flow of the design planning process?
- how is it described?
- what resources and competencies are required?
- what part of the design will be outsourced?
- who is responsible and are the authorities defined?
- how are (internal and external) interfaces between various groups identified and managed?
- are the required verification, validation and review points defined?
- are the main milestones and timelines identified?
- is the implementation and effectiveness of the plan monitored?
- is the plan updated and communicated to all relevant functions as necessary?

4. Auditing design and development inputs

When auditing the design and development inputs, auditors should develop an understanding of how the organization identifies its own inputs based on:-

- the organization's products and processes;
- financial, environmental, health and safety issues;
- organizational risks and impacts;
- customer's requirements and expectations;
- statutory and regulatory requirements applicable to the product .

Auditors should evaluate the risks, the possible implications for customer satisfaction and issues that the organization may encounter if some relevant inputs are not considered.

5. Auditing the design and development process and design reviews

Auditors should verify that the overall design and development process is controlled in accordance with the organization's original plan being reviewed and that the design and development reviews take place at appropriate planned stages.

The following issues should be considered by auditors when examining the review process:-

- do reviews occur at planned stages throughout the design process?
- are the reviews carried out in a systematic way involving representatives of the functions concerned with the stage(s) being reviewed?
- have all original and any new inputs been considered ?
- are the original outputs still relevant or have revised outputs been identified?
- have revised inputs and outputs been reviewed and approved by those with the relevant responsibility and authority (including the customer where appropriate)?
- does the output demonstrate the suitability, adequacy and effectiveness of the designed product?
- are the relevant design objectives being achieved?
- are there adequate records of reviews?

6. Auditing design and development outputs

The design and development outputs should comply with the identified needs in order to ensure that the resulting product can fulfil its intended use. Outputs can include information relevant to the following:-

- marketing, sales and purchasing;
- production;
- quality assurance;
- information for service provision and maintenance of the product after delivery

and, should be provided in a form that enables verification and validation activities to be performed.

Auditors should obtain evidence from the projects selected to confirm that:-

- information regarding the completion of design and development stages is available;
- the design and development process has been completed for the stage under review;
- design and development outputs have been confirmed

7. Auditing design and development verification

Design and development verification is aimed at providing assurance that the outputs of a design and development activity have met the input requirements for this activity as shown in Figure 2 below.

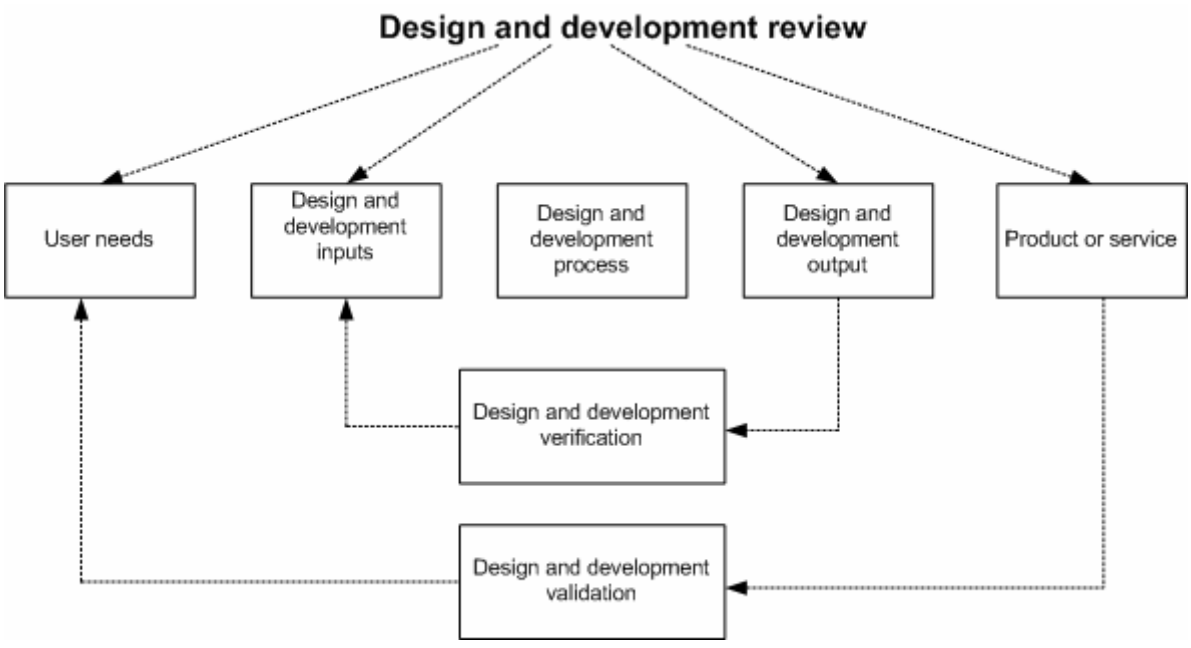

Figure 2

Verification can comprise activities such as:-

- performing alternative calculations;
- comparing a new design specification with a similar proven design specification;

- undertaking demonstrations including prototypes, simulations or tests; and,
- reviewing documents prior to issue.

Auditors should determine that the design and development verification activities should provide confidence that:-

- required verifications are planned and that verification is performed as appropriate during the design and development process;
- the completed design or development is acceptable and the results are consistent with and traceable to the initial requirements;
- the completed design or development is the result of implementation of a proper sequence of events, inputs, outputs, interfaces, logic flow, allocation of timing, etc;
- the design or development provides safety, security, and compliance with other requirements and design inputs;
- evidence is available to demonstrate that the verification results and any further actions have been recorded and confirmed when actions are completed.

Auditors should determine that only verified design and development outputs have been submitted to the next stage, as appropriate.

8. Auditing design and development validation

Design and development validation is the confirmation by examination, and the provision of evidence, that the particular requirements for specific intended use are fulfilled. In other words, is the validation process capable of checking that the final product and/or service will meet, or does meet, the customer's needs when it is in use ?

Validation methods should be specified as part of the design and development planning process, although these could be modified during the realization of design and development.

For many products and/or services, validation is relatively simple process. An example could be a new design of office furniture, which could be validated by the testing of prototypes, followed by testing of initial samples of the finished product.

However, in many other situations, design validation will be more complex. For example, the products or components used in electric or electronic systems may have to comply with several performance requirements established by other system design organizations. In such a situation, design validation can only be completed by obtaining information about the performance of the products or components (preferably formal test results) from such system design organizations or by users of the products or components.

Another example of a difficult situation is when design validation is performed by the client or some other external organization (e.g. for the confirmation of architectural and engineering designs).

In such complex situations, the organization will need to seek agreement with the relevant external parties as to how design validation will be performed and the results communicated to and shared with it. In such a situation, provision should be incorporated into the organization's design and development planning for completing design validation in this manner.

Auditors should ensure that:-

- there are records to confirm that the validations have been carried out;
- the validation was carried out in accordance with the planned arrangements for validation;
- the validation indicates that the resulting product is capable of meeting the requirements of the specification;
- wherever practical, the validation has been carried out prior to delivery or implementation; and that,
- there are records of any actions necessary to correct non-compliance with the design and development inputs and the reasons for these deviations.

Where validation cannot be carried out prior to delivery or implementation, auditors should ensure that these activities are carried out at the earliest opportunity, such as when commissioning a complex plant or factory, and that this is communicated to the client. Auditors should determine that only validated design and development outputs have been submitted for customer use.

9. Auditing design and development changes

Design and development changes made during the design process need to be controlled. Auditors should consider the following :-

- are the sources and requests for changes properly identified and communicated?
- is the impact of any change evaluated?
- is any additional design proving or testing undertaken where appropriate?
- are the effects of the changes on constituent parts and product already delivered evaluated?
- has appropriate approval been given before a change is implemented (this could include statutory or regulatory approval or approval by the client)?
- are the changes fully documented and do records include information regarding any necessary additional actions?

Date: 8 December 2006

ISO 9001 Auditing Practices Group

Guidance on cultural aspects of auditing

Introduction

During the course of their career, auditors may be required to audit organizations with vastly different internal "corporate" cultures, and in varying ethnic, social, economic, political, or religious cultures.

It is important for auditors to be sensitive to these cultural issues in order to avoid possible conflict, but at the same time remain impartial in carrying out the audit and achieve the objectives of the audit.

Auditors also need to be able to express themselves in terms that will be understood, especially where language is an issue. It is important to remember that it is the auditors' responsibility to adjust to the auditee's language skills and that a lack of language skills by auditees should not prejudice the audit outcome. Also, there may be different cultural and language aspects in separate parts of an organization, for example in multinational corporations.

Guidance

Cultural aspects need to be considered during all stages of the audit.

1）Audit planning

a. The best place to begin to consider possible cultural aspects of the audit is during the planning stages. This may include:
    i. Audit team selection (personal characteristics including gender; language abilities; social skills; potential cultural conflicts)
    ii. Audit schedule (respecting typical working hours, traditions, holidays, meal times, prayer times, etc. whenever possible)
    iii. Considering the need for independent translation and to allocate extra time
    iv. Making the audit team aware of any areas of potential cultural sensitivity

b. Whenever possible, it is desirable to use auditors who are familiar with local languages and customs. Alternatively, it may be appropriate to seek guidance prior to conducting the audit.

c. Any significant cultural aspects should be evaluated during a Stage 1 Audit and it may be appropriate to make modifications prior to Stage 2 and subsequent audits.

2) Internal "corporate" culture.

All organizations are different and there is no “standard” corporate culture. The internal culture may be independent of the external culture in which the organization exists. There are many aspects that need to be considered. The following are some examples.

a) Degree of formality / Dress code

Auditors may be put at a psychological disadvantage if he or she is dressed too informally, and most certification bodies have dress codes in place to address this. Equally important, however, and often overlooked, is the possibility for auditors to be “over-dressed”, thereby running the risk of being uncomfortable, or inhibiting the auditee and affecting the audit outcome. A useful tip when preparing for an audit is to “dress like the organization’s directors”. Auditing a farm in a tropical country requires a vastly different dress code than auditing an investment bank in a major financial capital in a cold climate. Pre-audit visits, Stage1 audits and basic common sense are all useful tools in determining what style of dress is appropriate.

b) Organizational hierarchy

It is important to recognize that ***formal*** does not necessarily mean ***good*** and ***informal*** does not necessarily mean ***bad***. Some of the best-run organizations are very informal in their management style and, in particular, their hierarchical interactions and communications.

Auditors need to be sensitive to the organizational protocols with respect to organizational hierarchies, but should not be inhibited from communicating directly with the person who is actually doing the work. The tendency to “only talk to the manager” should be avoided at all costs, though it may be necessary to give the manager some extra face-to-face time, in order to avoid embarrassment.

c) Approach to negative audit findings

It is important for any and all nonconformities identified during the audit to be properly documented and presented to the organization (see also the APG guidance on “Documenting a nonconformity”). Some organizational cultures are highly sensitive to and defensive of nonconformity reports, and in some situations, management may seek to assign blame to the “persons responsible”. This can create added tension during the audit, but should not deter Auditors from raising such nonconformities. It may, however, be appropriate to re-emphasize the fact that the audit is aimed at verifying the system and not individuals - this should already have been mentioned during the opening meeting.

3. External (local or regional) culture.

It is not realistic to provide detailed guidance on all the cultural situations that auditors may need to address, however some basic guidance will always be useful. This might include, for example:

- Language
- Eating and drinking habits
- Social inequalities
- Gender sensitivities
- Style of dress
- Body language

- Self respect and national pride (and in particular the attitude towards receiving NC's)
- Religious beliefs, and dates of key religious festivals or holidays
- Local customs
- Sensitive political issues

In general, the golden rule for auditors is never to get involved in religious or political discussions, but an awareness of these and other potential cultural aspects prior to the audit can help prevent embarrassment or conflict at a later stage.

Auditors should always try to be accommodating to the local culture, but in doing so, should ensure that this does not affect the audit objectivity and outcome.

Date: 8 December 2006

ISO 9001 Auditing Practices Group Guidance on:

"Output matters!"

1. Introduction

The ISO 9000 Advisory Group (comprising representatives from ISO/TC 176, ISO/CASCO, ISO/COPOLCO, IPC and the IAF) has recently made a number of recommendations to address increasing concerns that certified organisations are not delivering consistent, conforming product complying with customer requirements (ref. ISO 9001:2000 clause 1.1.)

The following paper by Jack West, first published in the July 2006 issue of Quality Digest magazine, addresses this topic and emphasises the theme that "Output matters!"

Conformity to individual requirements of ISO 9001:2000 such as document control, control of records, personnel competence and calibration of measuring equipment are important, but should not be the central focus of a quality management system. They should be seen as a means of achieving the desired output, which is consistent, conforming product.

2. Jack West's Paper

It's often said that an organization can have a good quality management system (QMS) that conforms to ISO 9001 and yet still produce "junk." This observation derives from the perfectly valid distinction between third-party registration of a QMS and product certification. Certifying a QMS is no absolute guarantee that the product produced by the certified organization will be in conformance with requirements. Nonetheless, ISO 9001 contains many requirements that, taken together, should provide reasonable assurance that a system's output will meet customer requirements.

ISO 9001 requires that an organization's quality policy include commitments to meeting requirements and continually improving its QMS. The standard requires that product designs be validated to ensure they will meet requirements for given applications. ISO 9001 also requires that a product be verified to ensure it meets requirements. Identifying and meeting customer requirements is a consistent theme throughout ISO 9001. For example, one of the expected outputs of a management review is a decision regarding product that doesn't meet customer requirements.

ISO 9001 Clauses Demonstrating That Output Matters	
1.1 "Scope"	"This International Standard specifies requirements for a quality management system where an organization a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and

	b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements."
5.2 "Customer focus"	"Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1)."
5.3 "Quality policy"	"Top management shall ensure that the quality policy … b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system …"
5.6.3 "Review output"	"The output from the management review shall include any decisions and actions related to b) improvement of product related to customer requirements …"
6.1 "Provision of resources"	"The organization shall determine and provide the resources needed b) to enhance customer satisfaction by meeting customer requirements."
7.2.1 "Determination of requirements related to the product"	"The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization."
7.3.2 "Design and Development inputs"	"Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include a) functional and performance requirements …"
7.3.6 "Design and development validation"	"Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. …"
8.2.1 "Customer satisfaction"	"As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. …"
8.2.4 "Monitoring and measurement of product"	"The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. …"
Material quoted from ISO 9001:2000, used by permission of ISO	

We need to stop perpetuating the myth that organizations can truly be in conformance with ISO 9001 and still produce product that doesn't meet customer requirements. ISO 9001-registered organizations and auditors alike tend to focus on conforming to the details of ISO 9001 and often lose sight of the basic requirements. Never lose sight of the product! A claim that an organization conforms to ISO 9001 should mean to the organization's customers that it can consistently provide product that meets customer requirements.

We must make certain our systems deliver conforming product to our customers. The standard requires it, and the credibility of ISO 9001 registration demands it. It's the output of our QMS that matters to our customers.

Note: This article summarizes several important concepts related to ISO 9001:2000 that are explained in more detail in ISO 9001:2000 Explained, Second Edition *by Charles A. Cianfrani, Joseph J. Tsiakals and John E. (Jack) West (ASQ Quality Press,2001).*

About the author

John E. (Jack) West is a consultant, business advisor and author with more than 30 years of experience in a wide variety of industries.

Date: 2 July 2007

ISO 9001 Auditing Practices Group Guidance on:

Auditing the Procurement and Supply Chain Processes

1. Introduction

When developing a management system, many organizations will have put in place systems to control the purchasing of products and the verification of purchased products in a way in which they consider satisfies the requirements of Clause 7.4 of ISO 9001:2000. Similarly, Auditors may consider it sufficient to confirm compliance by checking that an approved supplier list is up-to-date, that orders have been placed only with approved suppliers and activities necessary for ensuring that meeting specified purchase requirements have been carried out.

In many instances, however, that may not be sufficient to ensure that purchased products simply meet original specifications in all respects. In such instances, it would be preferable to review the wider processes for procurement management and the supply chain.

2. Auditing the Procurement Process

In auditing the process for the management of procurement, the following should be considered:-

- Procurement starts during the design and development of a product when a specification is prepared;
- Inter-departmental discussions take place to ensure that potential suppliers can provide a product that meets the design specification at the required cost;
- The organization should ensure that the specified purchase requirements are correct prior to their communication to the supplier;
- Statutory & regulatory requirements have been included in the purchase requirements; and,
- The degree of risk associated with a component product and the controls required to ensure that it meets the design specification have been assessed.

Practical suggestions of ways in which to confirm that the above points have been considered are:-

- Confirm that the specification quoted in a purchase order is the same as the specification contained in the design (or the specification received from the customer);
- Identify whether or not there were discussions between the organization and potential suppliers regarding the design specification of critical components during the design process or prior to an order being placed;
- Was there some form of “approval” of the specification before the final specification/order was confirmed to the supplier?

- Does the purchase order contain or refer to any statutory or regulatory requirements?

3. Auditing the Supply Chain

In many cases, audits of the evaluation and selection of suppliers simply consists of a review of the organization's approved supplier list and whether this list has been reviewed at regular intervals. In many cases this may not be sufficient to ensure that the organization has effective control of all of those suppliers within its supply chain. Issues to consider are:-

- Are suppliers of critical component products selected based only on their ability to supply at an economical price or is their ability to supply consistently to specifications also taken into consideration?
- Are suppliers included in approved lists solely on their continued registration against a recognised quality standard or is the scope of this registration reviewed?
    - Note: In some cases, it may be advantageous for the organization to audit the intended supplier to establish clear lines of communication, product specifications, delivery parameters, etc.
- How frequently are credit notes raised by the organization for product rejected but subsequently accepted by the organization?
- How many concessions have been raised allowing the organization to accept previously rejected products?

4. Conclusion

Generally, for an experienced auditor, reviewing the procurement process and supply chain of an organization is straight forward common sense but there are situations where the nature of the product and components may indicate that additional investigation is necessary. Every product is unique just as all audit situations are unique.