



国际标准化组织



国际认可论坛

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认可评审实践组指南：

适用于认可评审员和评审组的能力准则

本文对认可机构如何确定和评价所使用的评审员及评审组的能力要求提供了指南，以提高认可过程的有效性和促进不同的认可机构遵循统一的方法。

1. 能力准则

概括地说，认可评审员应当：

- 熟悉相关的认可和合格评定标准以及他们所服务的认可机构的认可程序；
- 接受过适当的职业培训；
- 对不同的评定方法有充分的了解和理解；
- 具有评审员职业所需的适宜的经验 and 技能。

对上述准则的应用指南在 ISO19011 中可以找到。

一位认可机构评审员应该能够运用基于过程的方法来进行评审，应该有能力理解合格评定机构（CAB）的过程和它们与相关国际标准的要求及指南的关联。此外，认可机构评审员应该有能力将不符合或不足之处追溯到 CAB 的过程或管理体系（见 AAPG 指南《基于“过程方法”的认可评审》）。

认可机构应确定进行认可评审（根据需要，包括办公室评审及见证活动）所需要的能力准则。能力准则在主任评审员、评审员及实习评审员之间可以有区别。能力准则应该基于 ISO/IEC17011（**编译者注：该标准已等同转化为 GB/T27011 合格评定 认可机构通用要求**）的要求制定，并应该经认可机构的决策部门核准。

能力准则的条款中可以规定基本（通用）要求和特定要求（与特定的方案和领域及其他特定功能相关）。

在以下不同能力准则中，强调了认可机构为某次特定的评审而选择它的评审员和评审组时应该考虑的问题：

基本（通用）

a) 程序和标准

- 对认可机构程序的了解；
- 对认可机构标准（ISO / IEC 17011）和适用于评价 CAB 的标准（ISO / IEC17021、ISO / IEC 指南 65、ISO / IEC 17024、ISO / IEC 17020）及相关的 IAF 强制性和资料性文件的了解。

- 对 ISO19011 的了解。

b) 个人素质（见ISO19011）

应当使用各种不同的方法评价评审员的个人素质。评价结果应该被用于决定评审员实施特定的评审或评审组的委派。

c) 通用的知识和技能

- 有能力理解 CAB 的业务流程，并评价这些过程；
- 作出判断的能力。

特定的

d) 与方案/行业相关的要求和法规要求

- 管理体系（MS）标准的知识，以用于管理体系认证认可方案；
- 理解/熟悉与产品、过程和技术相关的业务活动（经济和社会的）涵盖经认可的管理体系认证；

- 具有产品标准、生产技术、产品使用和相关问题的知识，以用于产品认证认可方案(*)；

- 具有适用于不同职业人员的标准和专有技术及有关技能的知识，以用于人员认证认可方案；

- 了解和理解相关工具和指南，以便能够确定 CAB 正确管理了适用的法规要求。

(*)经适当改编后的类似应用要求，用作对产品、过程、机械设备、设计等检查的认可评审。

评审员/评审组应当能够从以下方面推导出上述行业知识：

- * 他们在相关工业/服务领域中的直接工作经历，或
- * 在该领域中的教育、研究和标准化活动，或
- * 咨询和审核活动，或
- * 这些要素的组合。

当这些知识不够充分时，评审员或评审组应当获得专家的支持。

e) CAB 的特征由于被评审，在选择评审员/评审组时应当考虑这些特征，例如：

CAB 的规模大小、其运作单位的数量、涉足业务的国家等等……；

f) 文化和语言

在策划评审和决定评审员/评审组时，这些方面也应当认真考虑，对于跨国界的认可评审（包括办公室评审和见证审核）而言，这些方面尤为重要。

关于对评审组的要求，认可机构应确保评审组整体上具有为某特定评审所需的能力

- 参考条款 a) 到 f) — 包括任何可以认定需要的特定的专业能力。正如前述所提及的，评审组中也许有必要包括专家，以防在特定的专业技术知识方面没有可用的评审员。

2. 资格审查程序

评审员/专家的资格审查程序应当包括初步甄选、培训、持续培训并可能需要保持和持续确认能力的定期评价。评审员及专家需要：

- 选择（基于教育、知识、经验和拥有的技能）；
- 通过适当的培训课程或等效的方法，进行认可规则和方法及认可机构的认可程序、准则及任何相关规定的培训；
- 持续监视和通过适当的方法进行评价（见 ISO 19011）。

（HXQC 宋治民编译，仅供参考）

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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 Mandatory and Informative 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).