



## ADVISORY 3 指引3

### Recognition and Authority of Management Representative 管理层代表的认可和授权

This Advisory describes API's position on recognition and the authority of "management representatives" of licensed and registered organizations.

本指引描述了API关于被许可和注册组织“管理层代表”的认可和授权的立场。

The purpose of an API audit is to verify that an organization has implemented the quality management system and that the personnel responsible for maintaining the system have the necessary competence to do so and are actively engaged in the process. The API audit also verifies the organization's manufacturing and service provision capability. In order for API to properly evaluate an organization, it is extremely important that API and its auditor(s) have direct communications with the personnel that are responsible for handling the quality management system issues at the facility on a daily basis.

API审核的目的在于验证一家组织是否执行了质量管理体系，且负责维护该体系的人员是否有胜任该项工作的能力以及是否积极参与其过程。API审核还验证该组织的生产和服务提供能力。为了使API能够适当地评估一家组织，API及其审核员必须能够每日与在该组织负责处理质量管理体系问题的人员进行直接沟通。

The Management Representatives of licensed and certified organizations must be appointed by the organization's management and be employed by the organization on a full-time basis. Consultants hired on a contract or temporary basis do not satisfy this requirement.

被许可和认证组织的管理层代表须由该组织的管理层委派，且应由该组织聘用为全职员工。合同制或临时聘用的顾问不满足此要求。

API does not approve or endorse third party contractors, and a licensee's choice to use or not use a particular contractor's services shall not affect their license status with API. Licensees are not required to use consultants. API auditors shall not require or recommend consulting services to meet the API program requirements.

API不批准或支持第三方承包商，被许可人选择使用或不使用特定承包商的服务不影响其与API的许可状态。被许可人未被要求使用顾问。API审核员不应要求或推荐满足API项目要求的顾问服务。

#### However, third parties are not permitted to:

但是，第三方不得：

- Act as the organization's management representative or point of contact;  
担任该组织的管理层代表或联系人；
- Interact with API staff or the API auditors, including asking questions of auditors, responding to inquiries on behalf of the licensee, or providing evidence of conformity with program requirements on behalf of the licensee;  
与API员工或API审核员互动，包括向审核员提问，代表被许可人回答问题，或代表被许可人提供符合项目要求的证据；

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- Respond to notices in the API MyCerts licensing system;  
答复API MyCerts许可系统中的通知;
- Provide translation services during the audit;  
在审核期间提供翻译服务;
- Interfere in any way with the progress of the audit, including by abusive or unprofessional behavior towards API staff or auditors; or  
以任何方式干扰审核进程, 包括针对API员工或审核员的侮辱性或不专业行为; 或
- Misrepresent to API that they are permanent or full-time employees of licensees.  
向API谎称其为被许可人的正式或全职员工。

Licensed organizations are responsible for ensuring their third party consultants' compliance with this Advisory. Violation of these prohibitions may lead to immediate suspension, termination, or loss of the right to use the API Monogram and registration marks.

被许可组织应负责确保其第三方顾问遵守本指引。违反这些禁止规定可导致使用API会标和注册商标之权利的立即中止、终止或丧失。

This advisory supersedes any previous version.

本指引取代任何之前的版本。

It is considered part of API's Program Requirements and is compulsory.

本指引被视为API项目要求的一部分, 且具有强制性。