



## ADVISORY 3

### Recognition and Authority of Management Representative

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

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.

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.

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.

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

- Act as the organization's management representative or point of contact;
- 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;
- Respond to notices in the API MyCerts licensing system;
- Provide translation services during the audit;
- Interfere in any way with the progress of the audit, including by abusive or unprofessional behavior towards API staff or auditors; or
- Misrepresent to API that they are permanent or full-time employees of licensees.

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.

This advisory supersedes any previous version.  
It is considered part of API's Program Requirements and is compulsory.