ADVISORY 3

Recognition and Authority of Management Representative and Use of Consultants

This Advisory describes Monogram/APIQR's position on recognition and the authority of "Management Representatives" of a licensed/registered organization and the role that a consultant or consultants may play in the organization's participation in the Monogram/APIQR Program.

For the Monogram/APIQR Program to properly evaluate a licensed/registered organization and its implementation and maintenance of its quality management system, the program and its auditor(s) must be able to communicate directly with the personnel that are responsible for handling the quality management system issues at the organization.

In accordance with API Specification Q1 and Monogram/APIQR policies and procedures, the Management Representative of a licensed/registered organization 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.

Regarding consultants, Monogram/APIQR neither approves nor endorses the use of third-party representatives (consultants); a licensed/registered organization's choice to avail itself of a consultant's services will not affect the status of the license/registration; and an organization is not required to use a consultant. Additionally, Monogram/APIQR auditors shall not require or recommend that an organization hire a consultant as a condition for meeting program requirements.

However, if third-party consultants are used by a licensed/registered organization to advise on meeting program requirements, the consultants are not permitted to do the following:
- Act as the organization's management representative;
- Act as the organization's point of contact in dealing with API staff or auditors;
- Provide translation services during an audit (note that this does not prevent the organization from using a translator during an audit that does not otherwise advise on program requirements);
- With respect to audits of the organization, interact with API staff or the API auditors before, during, or after the performance of the audit, including asking questions of auditors, responding to inquiries on behalf of the organization, or providing evidence of conformity with program requirements on behalf of the organization;
- Interfere in any way with the progress of the audit. This includes engaging in abusive or unprofessional behavior towards API staff or auditors; or
- Misrepresent to API that they are permanent or full-time employees of the organization.

Licensed/registered organizations are responsible for ensuring third-party consultants' compliance with this Advisory. Violation of the stipulations in this advisory may lead to immediate suspension or cancellation.

This Advisory supersedes any previous version. It is considered part of Monogram/APIQR Program requirements and is compulsory.