

ADVISORY 5

Requests for Exclusions to Quality Management Systems under the API Monogram Program

This advisory describes API's process for reviewing and granting exclusions from eligible sections of API Spec Q1, 7th Edition (*refer to Section 1.2.1, therein*), as applicable to an organization's quality management system.

1. The organization must provide a written justification for the exclusion.
2. The organization must identify the exclusion in their Quality Policy Manual (*reference API Spec Q1, 7th Edition, Section 4.2.2.a*).
3. The organization must demonstrate that controls are implemented for the transferring of API product specification requirements to process control documents (*reference API Spec Q1, 7th Edition, Section 7.5.1.2*).
4. The organization is not allowed to vary from the requirements of the API product specification. Variation from the API product specification(s) results in a product that is not eligible for the API Monogram and would likely reverse one's eligibility for exclusion.
5. The organization is required to provide evidence (during audits) that process controls are adequately implemented and maintained.
6. API (with objective evidence provided from the audit) has the final decision as to whether an organization is eligible for the requested exclusion.
7. If an exclusion is granted and later deemed ineligible, the organization is required to revise the affected Quality Policy Manual and ensure that such control features are maintained as verified by an audit.

If an organization requests an exclusion, they must provide API with a revised Quality Policy Manual (or sections) for review, using the above criteria. The organization will be notified of any eligibility for the exclusions and any required audit that must be performed prior to issuing the exclusion.

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