



ADVISORY 13

Supplementary Requirements for Design and Manufacture of a Product for Organizations Applying for a New Monogram License or for the Addition of Products on an Existing Monogram License

Facilities undergoing an audit for a new Monogram License or an additional product on an existing Monogram License shall provide evidence of the following during the audit:

1. Unless otherwise exempted by Advisory 6, designs for each monogram-eligible product within the scope of the API License as defined in API Spec Q1 and the product specification; and
2. Personnel competence, equipment, and procedures and documentation required to manufacture the product(s); and
3. Product realization documentation demonstrating the capability to perform the process(es) required to manufacture the product(s); and
4. During the audit, performance of manufacturing, inspection and test activities consistent with product requirements applicable to the addition or expansion of the Licensing scope.

Prior to release of a product (see API Spec Q1, clause 5.7) that has been marked with the API Monogram, the organization shall maintain evidence of a validated and approved design (see API Spec Q1, clause 5.4.7) in accordance with API Spec Q1 and the API Product Specification.

This advisory supersedes any previous guidance. It is considered part of API's Program Requirements and compliance is required for licensing and certification.