



## ADVISORY 13

### **Supplementary Requirements for Design and Manufacture of a Product for Organizations Applying for a New Monogram/API Repair and Remanufacture Program License or for the Addition of Products on an Existing License**

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

1. Unless otherwise exempted by Advisory 6, designs for each license-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) (Monogram) or repair/remanufacture the product(s) (API Repair and Remanufacture Program); and
3. Product realization documentation demonstrating the capability to perform the process(es) required to manufacture the product(s) (Monogram) or repair/remanufacture the product(s) (API Repair and Remanufacture Program); 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 or the API Repair and Remanufacture Program Mark, 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, when design is applicable.

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