Inquiries:
202-682-8000
api.org/ContactMonogram

March 21, 2022

ATTENTION: API Monogram Licensees
API Monogram Applicants

RE: 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

The API Monogram Program will issue a new Advisory on May 2nd, 2022 clarifying the requirements for organizations that wish to apply for a new Monogram License or an additional product on an existing Monogram License that includes satisfying design and manufacture activities in accordance with the applicable product specification and API Specification Q1. This advisory was developed after consultation with the Monogram Program Board.

Once Advisory 13 is published, the following evidence will be required and reviewed during the audit for Monogram participants, both when applying for a new License or when adding products to an existing License:

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 5.9) that has been marked with the API Monogram, the organization shall maintain evidence of a validated and approved design (see API Spec Q1, clause 5.4.6) in accordance with API Spec Q1 and the API Product Specification.

While the above information is always required to be maintained by the Licensee, an API auditor might not specifically request this information for existing products.

API has developed the following questions and answers to help clarify the intent and expectations of this Advisory:

Q: Is the applicant facility required to manufacture a prototype to be granted a Monogram License?
A: There is no requirement for a prototype. Organizations may elect to manufacture a prototype in conformance with their design validation requirements.

Q: My organization intends on completing design validation following our first order after the API audit. Can I be granted a Monogram License in this scenario?
A: Design Validation does not need to be completed prior to the API audit; however, it must be completed prior to product release conforming to API Spec Q1, clause 5.9 if the Monogram is applied to the product.

Q: What parts of the design must be available during the audit?

A: Monogram Program requirements state that all parts of design per API Q1, Section 5.4 must be satisfied when design applies to a monogram-eligible product. If designs are not performed at the licensee/applicant location, it is still necessary to show that all requirements of design have been satisfied and to provide answers to questions when posed by the audit relevant to those designs. If Design Validation has not been completed, all parts of the design controlled by the organization planned to be performed prior to design validation (whether on-site or outsourced), including Designing and Development Planning (API Spec Q1, 5.4.1), Design and Development Inputs (5.4.2), Design and Development Outputs (5.4.3), Design and Development Review (5.4.4) and Design and Development Verification and Final Review (5.4.5) will be reviewed by the API auditor. if Design Validation is performed after the audit is completed, the results will be verified on the next audit, even if product has already been delivered to the customer.

Q: Is evidence of personnel competence, equipment, and procedures and documentation acceptable if it is for other, similar, non-monogrammable products?
A: Regardless of how it may or may not apply to non-monogrammed products, the evidence provided must be applicable to the specific product(s) the organization is requesting to be added to its Monogram License, including all quality control, equipment qualification and maintenance and personnel qualification requirements.

Q: Can I use product realization documentation from a sister facility to satisfy requirement #3?
A: Licensing is based on activities performed at a specific facility location; therefore each facility must develop and maintain evidence of its own manufacturing capability, as required by Advisory 11 and the Monogram License Agreement. However, this does not prevent a facility from using shared or joint documentation across all corporate locations as long as the documentation is specific to the activities of the licensed facility.

Q: Can I demonstrate manufacturing activities and manufacturing capability using other products that are not Monogrammable?
A: There are no limitations on how a facility needs to demonstrate its overall manufacturing capability as long as it can be shown how the specific activity would apply to the manufacture of the monogrammable product. Manufacturing capability can be demonstrated through a variety of ways, including but not limited to prototype manufacturing or a compilation of product manufacturing whereby applicable processes have been performed by the facility.

Q: What type of manufacturing activities must my facility demonstrate during the initial audit?
A: The facility must demonstrate activities that are consistent with and relevant to the products in the Scope of the Monogram License. When there is an expansion of scope of an existing Monogram License or an existing product (e.g., increase in PSL), the demonstrated manufacturing activities must be relevant to the change.

Sincerely,

Kevin Ferrick

Kevin Ferrick
Director, API Monogram Program /APIQR

KF:hh