Regulatory Basis:
FDA Quality Systems Regulations

Reference: FDA CFR - Code of Federal Regulations Title 21

General Discussion
This procedure provides document for allowing *Vendor's* Material of Construction (MOC) documentation, such as Certificates of Analysis (C of A) and other record documents, to be accepted as confirmation that a specified material has been used for new systems or components that come into direct contact with product. This document also provides considerations for MOC verification for Critical Components of Legacy Direct Impact Systems.

Documenting MOC for critical components where MOC may impact product quality is an expectation of the Commissioning and Qualification process. While MOC documentation is a good engineering practice during commissioning for all components of direct, indirect and no impact systems, the intent of this document is to provide specific guideline for product contact critical components of new and existing direct impact systems only.

Vendor-supplied documentation of material of construction is generally sufficient documented evidence for confirming that a specified material has been used in construction of the delivered system or component.

Materials of Construction for critical components (e.g., product contact) in both manufacturing and utility systems should be suitable for their intended use, in that they should:

- Be compatible with the product and any cleaning, passivating, sanitising/sterilizing agents.
- Be smooth and cleanable (where required).
- Be resistant to temperature extremes (if applicable).
- Not have Particle release (be low or non-fibre shedding).
- Not contribute foreign substances to the product.
- Be non-absorptive.
- Meet surface finish levels, where required and specified.

Considerations for New Direct Impact Systems and their Critical Components
For new Direct Impact Systems and their related Critical Components (1), evidence of the suitability for intended use based on the materials of construction that come into direct contact with the product is obtained and confirmed during the Commissioning phase. The focus should be on components where the MOC could present a risk to product quality. Thus, the documentation criticality is higher where there is more risk that inappropriate alloys or materials may be present (such as custom-fabricated equipment where alloy, welding details or surface finish specifications are pertinent to protecting the product.)

At this stage of the process, Component Level Impact Assessments (CLIA) are conducted. CLIAs will identify components that have direct product contact and Commissioning Plans are then developed which will include critical and non-critical components requiring MOC verification.

The System Level Commissioning Plan also indicates which Commissioning Check-lists are to be completed; for example "Receipt Verification", and documents when they will be completed; i.e.: during Factory Acceptance Testing or during on-site testing. The check-lists incorporate references to adequate methods of material of construction verification for both critical and non-critical components and equipment.

Procurement Phase:
During procurement, documentation requirements, vendor-based commissioning requirements, and equipment and material specifications, are included in purchase orders and contracts. Vendor and Contractor pre-Qualification activities also take place during this phase.

Construction and Commissioning Phase:
Material receiving and associated inspections, including relevant documentation such as MOC verification, are carried out during this phase, as specified in the System Level Commissioning Plan.

Qualification Phase:
The IQ section of the Qualification Phase, confirms that the commissioning activities are complete, including the verification of materials of construction for direct impact systems and their critical components.

Considerations for MOC Verification for Direct Impact Systems and their Critical Components

If the material of construction (MOC) of a direct-impact system and/or related product-contact critical component is required, but is not known, there are a number of different approaches which can be used to determine the MOC. The following approaches are recommended for verification of MOCs for direct-impact systems and related critical components.

Assessment of Documentation
The level of effort justified to ascertain and document MOC for legacy system components should be related to the risk to product quality represented by the components. For example, metallic piping of nearly any specification is suitable for handling many solvents used in pharmaceutical manufacture. In some cases, therefore it may be unjustified to ascertain the specific MOC for such a system, as the risk to product quality is low.

It is often possible to verify an unknown system or component MOC by collection and review of supporting documentation. This is the first choice option that should be pursued where possible. Through assessment of existing documentation related to the design, purchase and/or maintenance of the system or component, evidence of the material used in construction can usually be found. The compatibility of the system or component with materials used during processing can then be evaluated to confirm suitability for intended use. The following documentation can be examined to provide evidence of the material of construction of a system or component:

- Purchase ledgers/orders – Procurement records often include model, serial number and

Intermediary - An Organisation which is supplied with products by the manufacturer and which then in turn supplies them to another company without further processing and without changing the properties specified in the purchase order and referenced product specification.

Non-specific inspection
Inspection carried out by the manufacturer in accordance with their own procedures to assess whether or not products defined by the same product specification and made by the same manufacturing process are in compliance with the requirements of the order.

Specific inspection
Inspection carried out before delivery according to product specification. Inspection of the products to be supplied, or of test units of the products, to verify that they comply with the purchase order.

