

1.0 PURPOSE

To provide standard guidelines for determining the acceptability of new, modified, or transferred components and assemblies.

2.0 SCOPE

All associates involved with the processing of first article reports.

3.0 REFERENCES/ATTACHMENTS

- [06fm004](#), First Article Report
- [13ti004](#), Defective Material Report
- [20ti002](#), Use of Gage Repeatability and Reproducibility (R&R) Studies
- [20ti003](#), Process Capability Studies

4.0 DEFINITIONS

First Article – An initial production run of material submitted by an external vendor to confirm their manufacturing capability for that material.

Note: Prototype material and engineering samples are **not** First Articles. First Articles are production, stockable materials only.

5.0 TASK INSTRUCTION

5.1 Risk Determination:

5.1.1 In order to ensure that a supplier will be able to consistently manufacture material to specification without incurring unnecessary inspection time and labor, the First Article inspection requirements shall be based on an evaluation of the part risk.

5.1.2 Material risk will be determined by the complexity of the material versus the manufacturing capabilities of the supplier using the following risk chart:

	SUPPLIER CAPABILITY	Certified Supplier Producing Similar or More Complex Material	Uncertified Supplier Producing Similar or More Complex Material	Certified Supplier Producing Less Complex Material	Uncertified Supplier Producing Less Complex Material
MATERIAL COMPLEXITY					
Critical to Safety of User / Patient or Proprietary Process					

High Complexity	II	I	I	I
Moderate Complexity	III	II	I	I
Off-the-Shelf / Low Complexity	III	III	II	I

5.1.3 Material complexity should be determined based on the capability of the process or machine used to produce the material. For standard processes and machines (i.e., CNC lathe, wave soldering, etc.) a process capability study does not need to be performed. For unique or proprietary processes, injection molding, tolerancing approaching traditional machine limits, etc., process capability studies should be considered based on the safety, efficacy, reliability, and financial risk associated with out-of-specification material. The risk should be obtainable from the risk analysis performed during the design cycle of the parent product. Process capability studies are only mandatory when required by other instructions.

5.1.4 Supplier capability should be determined based on the complexity of material that the supplier is consistently able to deliver within specification.

5.1.4.1 In general, new suppliers without a production history with Stryker Instruments shall be considered “Uncertified Suppliers Producing Less Complex Material” until a successful production history is established.

5.1.4.2 For off-the-shelf material produced in high volume or for consumer use (i.e., standard resistors, diodes, washers, nuts, bolts, etc.) by a supplier not previously used by Stryker, the supplier may be considered an “Uncertified Supplier Producing Similar or More Complex Material” prior to a production history being established.

5.2 When to Perform FARs:

5.2.1 At the discretion of the responsible engineer, FARs may be required in the following cases:

- Significant change to the process used to product the material
- ECO to the material that significantly changes the complexity of the material

5.2.2 The FAR process is mandatory in the following situations:

- New material/parts (excluding factory supplies and factory consumables)
- New or remanufactured tooling for molded/casted material
- Supplier change
- Production equipment or significant process change to electronic assemblies
- ECO to an electronic assembly that alters the design, manufacturing process, or the BOM (part-to-print ECOs, typographical corrections, or administrative changes to the BOM – such as updating the manufacturer’s part number for a component – do not require FARs)

5.3 How to Perform FARs:

5.3.1 The responsible Quality Engineer, Buyer, and/or Product or R&D Engineer shall determine the risk level associated with the material.

5.3.2 The responsible Quality Engineer and/or Product or R&D Engineer shall determine the “Required Specifications” to be verified by the supplier and/or Stryker Instruments.

5.3.3 The “Required Specifications” page (not necessary for Risk Level III material) of [06fm004](#) shall be given to the supplier for completion. The “Required Specifications” page shall be filled out and returned, with the material under consideration, by the supplier.

5.3.4 [06fm004](#) shall be completed by the appropriate parties at Stryker Instruments and filed in the attribute chart for the material along with any required supplier data. A copy of the completed FAR form should be forwarded to the supplier. Required review and approval signatures are controlled on the form.

5.3.5 Unsatisfactory First Articles shall be handled per [13ti004](#). [06fm004](#) and supplier data shall still be filed in the attribute chart for unsatisfactory First Articles.

5.4 **Minimum FAR Requirements:**

5.4.1 Risk Level III Material:

5.4.1.1 The following are the minimum FAR requirements:

- No defects found during a Receiving Inspection operation performed using the attribute chart for that material
- (Electronic assemblies only) The material successfully passes the minimum required checks of the Electronic Assemblies section of [06fm004](#)

5.4.2 Risk Level II Material:

5.4.2.1 The following are the minimum FAR requirements:

- Certification from the supplier that the material meets all required specifications and measurement or test data from one piece of material showing in-specification readings for all required characteristics
- No defects found during a Receiving Inspection operation performed using the attribute chart for that material
- (Electronic assemblies only) The material successfully passes the minimum required checks of the Electronic Assemblies section of [06fm004](#)

5.4.3 Risk Level I Material:

5.4.3.1 The following are the minimum FAR requirements:

- Certification from the supplier that the material meets all required specifications and measurement or test data from one piece of material (clearly segregated from the remainder of the material) showing in-specification readings for all required characteristics
- No defects found during a Stryker Instruments re-measurement of all required characteristics of the segregated material
- No defects found during a Receiving Inspection operation performed using the attribute chart for the remainder of the material
- (Electronic assemblies only) The material successfully passes all checks of the Electronic Assemblies section of [06fm004](#)

05fm019, Rev. None