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## MATL-gd-40345

### *Supplier Change Management Guidelines*

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**Scope**

- Kalamazoo       Puerto Rico       Electronics  
 Ireland       Germany
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**Purpose**

The purpose of this guidance document is to

- Provide guidelines for when a Supplier Change Request Form is required and not required
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**Distribution**

QS Subsystem:      Material Control  
QS Subsection:      N/A

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**Definitions**

N/A

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**References**

N/A

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## INTRODUCTION

### Why was this document created?

These supplier guidelines explain when a MATL-fm-50015 Supplier Change Request Form (SCRF) is required. If there is ever any question as to the appropriate path to follow, suppliers should call Stryker Instruments to discuss the planned change prior to implementation. Changes must not be implemented prior to receipt of approval in writing by Stryker.

### How is this document used?

The supplier must notify Stryker Instruments using the SCRF for any planned change as outlined below. SCRF submissions must be submitted to the respective Stryker Instruments buyer for approval. Supplier must receive a copy of the approved SCRF signed by the appropriate Stryker representatives before implementing the proposed change.

Note: Stryker may subsequently elect to require a Production Part Approval Process (PPAP) for review and approval.

	<b>Requirement</b>	<b>Clarification or example</b>
1	Use of other material or construction than what was used in the previously approved part or product.	For example, other material or construction as documented on a deviation and not covered by an engineering change.
2	Any change to a manufacturing and/or assembly process validated by Stryker Instruments, whether intentional or not.	Any type of product, process, material, or inspection change to a line/process validated by Stryker. For injection molding and/or electrical assemblies, this includes any tool or equipment movement within the same plant, or to another plant. Any change in equipment, tooling, inspection method, gages, or the process, previously validated by Stryker Instruments.
3	Production from new or modified tools, dies, molds, patterns, etc., including additional or replacement tooling. (Note: This does not include perishable tools).	This requirement only applies to tools which due to their unique form or function can be expected to influence the integrity of the final product. It is not meant to include standard tools (new or repaired), e.g. standard measuring devices, standard cutting tools, etc.

4	Sub-tier supplier change for parts, materials, or services (e.g. heat-treating, anodizing, plating, or other finishing services).	Any change of subcontracted parts, materials and/or services that could potentially impact the Stryker part.
5	Production from tooling and equipment transferred to a different plant location, or transferred from an additional plant location.	Production process tooling and/or equipment transferred between buildings or facilities at one or more locations.
6	Production following refurbishment or rearrangement of existing tooling or equipment.	Refurbishment means the construction and/or modification of a tool or machine, or to increase the capacity, performance, or change its existing function. This is not meant to be confused with normal maintenance, repair or replacement of parts, etc., for which no change in performance is to be expected and post repair verification methods have been established. Rearrangement is an activity which changes the sequence of production or material flow. Minor adjustments of production equipment may be required to meet safety requirements such as, installation of protective covers, elimination of potential ESD risks, etc. These changes can be made without Stryker approval unless the sequence of production or material flow has changed as a result of the adjustment.
7	<p>Product and process changes related to components of the production product manufactured internally or manufactured by a sub-tier supplier that may impact fit, form, function, performance, and/or durability of the product.</p> <p><u>Note:</u> The supplier must concur with any sub-tier supplier's change request before submission to Stryker.</p>	Any change that may affect Stryker requirements for fit, form, function, performance, and/or durability requires notification. Note: Due to the complexity of assemblies and subassemblies the potential impact may be difficult to assess, therefore error on the conservative side and discuss proposed changes with Stryker if there is any question.

8	<p>Change in test/inspection method – new technique (no effect on acceptance criteria)</p>	<p>When requesting a test method change, the supplier should have evidence that the new method provides results equivalent to the old method.</p>
9	<p><b>Additional notification requirements for Stryker OEM suppliers:</b></p> <p>Any changes made to:</p> <ul style="list-style-type: none"> <li>- Products that affect electrical certifications</li> <li>- Products that could affect sterility, bioburden, or biocompatibility</li> <li>- Literature or Instructions for Use (IFU).</li> <li>- Product level appearance, performance or labeling.</li> <li>- Affect the packaging level appearance or package label(s).</li> <li>- Affect the packaging functional Specifications</li> <li>- Non-functional and nonappearance related to the packaging.</li> </ul>	<p><b>Definition Stryker Original Equipment Manufacturer (OEM) supplier:</b></p> <p>A developer/producer of a finished device (a device that is device suitable for use or capable of functioning, whether or not it is packaged, labeled or sterilized)</p> <p>An OEM may or may not:</p> <ul style="list-style-type: none"> <li>- Have a 510(k)</li> <li>- “Own” the design and/or specifications</li> <li>- Distribute a finished device</li> <li>- Provide the same device to a competitor</li> </ul>
10	<p><b>For critical consumables only:</b></p> <ul style="list-style-type: none"> <li>- New source of raw material</li> <li>- Change in formula</li> <li>- Revised process parameters</li> <li>- Change product composition and/or ingredient levels of the approved product.</li> </ul>	<p>Any changes which would normally be expected to have an affect on the performance of the product.</p>
11	<p><b>For a change that introduces the following into the manufacturing process:</b></p> <ul style="list-style-type: none"> <li>- Product of animal origin</li> <li>- Latex</li> <li>- Phthalates</li> </ul>	<p>Any changes of this nature will require review and approval from the biocompatibility specialist within the local Stryker site.</p>

**The supplier must submit a PPAP for approval prior to the first production shipment in the following situations unless Stryker Purchasing has waived the requirement in writing.**

1	A new part or product (i.e. a specific part, material, or color not previously approved by Stryker.)	Submission is required for a new product (initial release) or a previously approved product which has a new or revised part number.
2	Engineering change to drawings, specifications, or materials for production product/part number(s).	Submission is required on any engineering change to production product/part drawings, specifications or materials.
3	Correction of a discrepancy on a previously submitted PPAP part.	As directed, a re-submission may be required to correct a discrepancy on previously submitted parts. A discrepancy can be related to: <input type="checkbox"/> <ul style="list-style-type: none"> <li>- The product performance against the Stryker requirements</li> <li>- Dimensional or capability issues</li> <li>- Sub-tier supplier issues</li> <li>- Testing, including material, performance, engineering, validation issues.</li> </ul>
4	<b>For Critical Consumables only:</b> Any process technology new to the supplier, not previously used for the approved product.	

## Situations where Stryker Notification is Not Required

Stryker notification and/or submission is not required for the situations described below. In these situations the supplier is responsible for monitoring the changes and/or improvements to verify its impact on the part/process. The following examples are generally manufacturing and/or quality system situations and/or improvements.

Note: Stryker notification is required any time Stryker product requirements for fit, form, function, durability and/or performance may be affected. At times impact on fit, form, function, durability and/or performance can be difficult to determine. **If ever uncertain, notify Stryker.**

	Requirement	Clarification or example
1	Identical gage replacement.	Gages replaced as part of gage maintenance or calibration system.
2	<p>(<u>Note:</u> Stryker Instruments – Puerto Rico requires notification for any tool movement.)</p> <p>Tool movement within the same plant (i.e. used in equivalent equipment, no change in the sequence of production or material flow, no disassembly of the tool) or equipment, movement within the same plant (same equipment, no change in the sequence of production or material flow).</p>	<p><u>Exceptions:</u> Stryker Instruments – Puerto Rico requires notification for tool movements.</p> <p>Also, see Notification #2.</p> <p>Notification is required for Stryker validated processes/equipment. Based on lean manufacturing initiatives, some equipment is designed for mobility, i.e. on wheels with quick disconnects.</p> <p>Cell configurations or location within a department may be changed without affecting the sequence of production or material flow.</p>
3	Rebalance of operator job content with no change in production sequence or material flow.	Lean manufacturing allows for rebalancing job content to eliminate bottleneck issues.
4	<p><b>For suppliers developing a PFMEA only:</b></p> <p>Changes resulting in reduced RPN on PFMEA (with no change to the production sequence or material flow).</p>	Examples include added controls, increased sample size and frequency, and error-proofing installation.

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5	<b>For Critical Consumables only:</b> Tightening of Stryker acceptance tolerance limits.	Suppliers of Critical Consumables also need to notify Stryker Instruments of planned changes prior to implementation.
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