1.0 Purpose of Procedure

This document describes Product Resources' Product Process Analysis and Process Validation processes. It provides for procedures and assigns responsibilities.

2.0 Scope of Process

The scope of this process is analyzing a process and its flow for potential failure points and using a risk-based method for determining where action is needed. The scope of this process also includes the validation of select processes. The purpose in both cases is risk mitigation / risk management. Processes spoken about in this procedure are product processes and not QMS or general business processes.

3.0 Process Owner(s)

3.1 Engineering

3.2 Quality

4.0 Procedure

Product Resources deploys two methods for determining the robustness and/or correctness of a process, used alone or together depending on the product. They are process analysis with or without FMEA and process validation. The process for each follows:

4.1 Process Analysis and Process FMEA (PFMEA)

4.1.1 Process Analysis

Prior to completing a process FMEA, or instead of completing a process FMEA for a product that is not a medical device, it is recommended that a process flow be completed and reviewed with representatives of all impacted parties, typically Manufacturing, Engineering, and Quality. Review of a process in this manner can not only enhance awareness of the designed process but can also spot potential process problems, permitting the process to be altered or enhanced to avoid.

A process flow should consider the whole Product Realization process, including the verification of purchased materials or other oursourced processes.

4.1.2 Process FMEA

For each medical device product put into production, Product Resources shall complete a process FMEA, or PFMEA. The PFMEA shall examine failure modes that could occur at all points in the Product Realization process, including in the processes of Product Resources suppliers, in the verification of purchased materials, and in other outsourced processes. It shall assess these failure modes for their severity, for their likelihood of occurring, and for the ability to detect occurrence. For each failure mode, a Risk Priority Number (RPN) is calculated. On a 1000-point scale (10x10x10), RPNs of 200 or greater (by default, or otherwise a threshold RPN number agreed upon between Product Resources and its customer and/or included in a project-specific Quality Plan) shall require mitigation such that the RPN will be lowered to be under the threshold RPN score post-mitigation. In addition, severity scores of 8 or higher, regardless of the RPN, shall require mitigation.

When there are items in the PFMEA that require mitigation, the PFMEA shall be revisited to record the nature of the mitigations and to recalculate the RPNs. The PFMEA shall also be revisited upon significant change to product or process to determine if the change alters the PFMEA either by introducing new failure modes or by altering existing failure modes' severity, likelihood of occurrence, and/or detection ability. If so, the process described above is repeated for the new or newly scored items.

Form 80-3000 is used for the PFMEA. PFMEAs are electronically stored on the Engineering drive in the following locations:

1. PFMEAs completed as part of an engineering project are stored in engineering project space:
    - PFMEAs are stored in the project folder on Teams under project DHF → Risk Management → FMEA. These documents will be archived upon project completion per procedure 43-1804, Procedure, Closing a Project.
2. PFMEAs that are not completed as part of an engineering project, or after an engineering project has ended, are stored in continuing project space:
    - PFMEAs are stored on the file server → Engineering drive → [Customer] → [Product] → Current Product Definition → Risk → PFMEA. Once a PFMEA is completed in an engineering project, the project's final version will also be stored in this location for ongoing usage.

The completion of the PFMEA process is indicated in Product Resources' specific RTM procedure for medical devices, 43-4521.

ISO 14971 is available at Product Resources as an external standard and shall serve as guidance for Risk Management for medical device product, inside of Product Resources' scope.

While required for medical devices, a PFMEA may be undertaken for any Product Resources product or service based on a project scope of work or simply to improve a process.

4.2 Process Validation

It is required that the organization validate any processes for Production (or Service) for which the resulting output cannot be verified by subsequent monitoring of measurement. We will call these "special processes". Product Resources currently runs such special processes. Other processes may be selected for validation based on their criticality or based on a design/development project's scope of work.

It shall be the joint responsibility of Engineering and Quality Assurance to select the processes for validation and to validate a selected process to thereby demonstrate the ability of the process to achieve planned results. It shall be the responsibility of Engineering to provide procedures for the process in the product routing. It shall be Manufacturing's responsibility to maintain the process once put in place.

4.2.1 Developing the Validation Protocol

The form 80-3215 is used for process validation. Essential to the process validation process is the establishment of process requirements. The process requirements are itemized as R1, R2, through RX. Alternatively, an external process requirements document can be created and referenced. In all cases, requirements are numbered. After requirements are established, a test protocol

is developed. Test steps T1, T2, through TX are developed to collectively challenge the process. A test step will describe the test to be run and the expected outcome. Finally in developing the validation protocol, the requirements section is updated to link each requirement with the one or more tests that evaluate the requirement. The protocol is stored with a -VP suffix (meaning Validation Protocol) in its file name.

For medical devices, the protocol shall be approved prior to its execution.

4.2.2 Executing and Reporting On the Validation Protocol

For execution and reporting, a -VR file name suffix (meaning Validation Report) copy of the -VP protocol is made. An Evidence folder is made, optionally with subfolders named after the TX tests in the protocol for more complex protocols. As the tester comples the tests, supporting evidence is placed in the Evidence folder and actual outcome is completed in the protocol document, noting the supporting evidence.

The report is the completed -VR file and its supporting Evidence folder. The tester or responsible party completes the Conclusion portion of the form and ensures that all tests have a Pass or Fail determination. Required report approvals are the tester, the report author, and Quality.

4.2.3 Customer Approval of the Executed and Reported Validation Protocol

For medical devices, customer approval of the executed protocol (report) shall be obtained and record stored, to indicate customer acceptance of the process described in the validation package. This may be on our form or on the customer's form.

4.2.4 Re-Validation

If a process has already been selected for validation – is a validated process – then substantive changes to that process require a repeat of the validation or particular steps of the validation and may require that new validation steps be added. What is needed is dependant on the nature of changes and shall be sufficient to establish again that the process achieves planned results. It is the responsibility of Engineering and Quality Assurance to at the decision point in the ECN process (see also 43-2627, ECN Procedure) determine that a validated process is being impacted, to produce a suitable validation protocol for re-validation, and to use successful completion of the re-validation as a condition for ECN release. Requirements for approval of a re-validation are the same as for the initial validation. Customers may have a notification and/or approval requirement for changes to processes, and it is the responsibility of Quality Assurance to recognize and act on the requirement.

5.0 Control of Records

The storage location and retention period for records referenced above are given in 91-6002, Control of Records.