TABLE OF CONTENTS

1.0 PURPOSE and SCOPE

1.1 The purpose of this procedure is to establish a process to facilitate product and/or process change preparation, review, approval, and control of documentation managed by AMO Equipment Site's document control department.

1.2 The scope of this procedure applies to all controlled documentation generated through Agile pertaining to product and process managed by AMO Equipment Site. Agile is the electronic documentation management system tool used by AMO.

2.0 RESPONSIBILITY

2.1 Process Owner

The Director of Quality Assurance is the owner of the Change Control process.

2.2 Intended Audience/ Process Community

2.2.1 **All Departments at the Milpitas, Albuquerque and Sunnyvale sites responsible for performing roles associated with the Change Control process** shall comply and train to this document.

2.2.2 **Equipment R&D groups at the Santa Ana** site shall comply and train to this document as they are contributors to the equipment design control process change orders processed by Equipment Site's Document Control Group.

3.0 TERMINOLOGY

Refer to Abbott Quality System Glossary and Site Glossary for definitions of additional words within this document. To add or revise definitions contact the document owner.

Terms specific to this document are included in this section.

Terms or Acronym/Abbreviation	Definition
Administrative changes	Changes to: Item attachments, that include typographical error corrections, formatting corrections, and adding approved attachments omitted during release Item Master fields that include typographical error corrections, field value changes, such as LMS field, RoHS compliant field, and other field changes
BOM	Bill of Material
CIA	Change Impact Assessment
CO	Change Order
CR	Change Request
DDP	Design and Deliverables Plan
Interchangeable	When two or more parts possess equivalent functional and physical characteristics; when they are capable of being exchanged one for the other without alteration of the parts themselves or any adjoining parts, except for normal adjustments; and when they do not require selection for fit or performance, the parts are considered interchangeable.
Non-interchangeable	When a part is to be changed and the new part would not physically fit, function as a replacement for the old part in all applications of its previous revisions, have the same physical characteristics, or the old parts will not physically fit or function as a replacement for the new part, the parts are considered non-interchangeable.
OEM	Original Equipment Manufacturer - Supplier who manufactures for a customer a finished device to be kitted or included as part of a finished package by the customer
TPM	Third Party Manufacturer - Perform the procurement of parts and materials, assemble, test, final acceptance and packaging of Abbott products for shipment to commercial distribution on Abbott's behalf. Also known as Contract Manufacturers, these suppliers can perform all, part or combinations of the activities described above and other related activities, not listed above on Abbott's behalf.
Typographical errors	Transcription errors, not including quantitative figures expressed numerically: Misspelled, omitted or duplicated words, grammatical or punctuation errors which do not change the original intent or meaning of the sentence.
VRB	Validation Review Board
UOM	Unit of Measure

4.0 IMPLEMENTATION

All requirements will be fully implemented on effective date.

The new/revised requirements in this revision are to be implemented on Change Request/Change Orders initially submitted after this revision is effective. Exceptions are allowed for Change Orders related to projects currently in progress which are evaluated and approved through a Change

Request as of the date this revision is effective. All Approved or Released CRs are to be closed according to requirements implemented in this revision.

5.0 REQUIREMENTS

5.1 General Overview:

5.1.1 The Change Request or Change Order is the vehicle for the change originator to record complete and accurate information to the Change Control representatives (Approvers).

5.1.2 The Agile software is the electronic system used to document, initiate and control revisions to product documentation and quality system procedures. The term "Change" refers to both new product development and the modification of existing products and its documentation.

5.1.3 Access to Agile and the ability to create, view and approve an item or change order is managed through IT. Authorization is signified by the functional area management approving the IT department's Customer Support Services (CSS) form.

5.1.4 A Change Initiator initiates and manages the Change through to closure. The Initiator is responsible for change impact assessment, develops the change plan task/action item, and completes assigned tasks. The change initiator must know what is required to control the change, who are the impacted functional areas, and where to obtain information.

5.1.5 A Change Impact Assessment (CIA) is the evaluation of the change's impact to any other part that uses it, any procedure or document that indicates its use, functions affected by the change, or a function's activities as well as regulatory impact (i.e. submissions, applications, supplements, etc) processed through Change Orders (COs, CRs and MCOs). The CIA is documented in the CO through the use of the CIA form and indicated in the Change order. Not all Change orders require a CIA, see section 5.2.6 for MCO exceptions.

5.1.6 Change Control Board – refer to MIL-05-S003 for details regarding CCB. In general, Change Control Board (CCB), members performs review for completeness and approves the change impact assessment, and reviews change for fulfilled requirements in the document control system. Unless specified, CCB review and approval will be by CCB, as defined by the change.

5.2 Change Type Overview:

5.2.1 A **Pre-Market Change** applies to COs released for Design Outputs of product(s) or process(s) run under EQP-08-S100, Medical Equipment Lifecycle Management Procedure, prior to the Pre-Market Design Review and Approval (market launch).

5.2.1.1 Changes to parts affecting both Pre-Market equipment and On-Market equipment shall meet the requirements for both uses.

5.2.1.2 Source Control Parts (i.e.: Source Control Document (SCD)) and their associated documents are not considered Pre-Market Changes. Source Control Part follows the On-Market Change requirements.

5.2.2 An **On-Market Change** applies to CR/CO released for Design Outputs of product(s) or process(s) that are currently released to the market. Requirements are documented in this procedure.

5.2.3 Changes are categorized relative to the potential impact on the product.

5.2.3.1 Category 1 – Changes impact the form, fit or function of the product (part) or process.

5.2.3.2 Category 2 – No effects on form, fit or function of the product (part). Justifications to support this assessment are to be provided.

5.2.4 **Change Request (CR)** is intended for changes that impact product design change and/or process design change. It includes the essential assessments and impacts regarding the proposed change related to risk, Regulatory, qualification/validation and Environmental Health and Safety. A Change Request (CR) that is approved is intended to authorize one or many Change Orders or Manufacturer Change Orders (CO/MCO) necessary to implement the release/change. CRs used for project related activities would be categorized according to the overall impact assessment.

5.2.5 **Change Order (CO)** is used to implement changes to documents as a result of a Change planning or a low impact change (i.e. as identified from the Pre-defined Low Impact list, MIL-05-S014).

- A part or document's lifecycle is controlled through the use of Change Orders (COs and MCOs).
- An assessment of the impact of the change is to be documented in the Change Order (or assessment attached to the CO). Items being made obsolete are to be assessed for their impact to other documents or parts through the use of Relationships and Where Used function. Changes to those items found as part of this process may require a change.
- Release of BOMs for use in Production is done using a Change Order (CO). The BOM will be automatically transferred to SAP upon release of the Change Order (CO).

5.2.6 **Manufacturing Change Order (MCO)** is used to update items which have previously been released via a CO.:

MCOs are considered low impact changes, with the exception of lifecycle changes, i.e. Pilot to Production lifecycle. Refer to MIL-05-S014 for required CIA elements to be included in MCO.

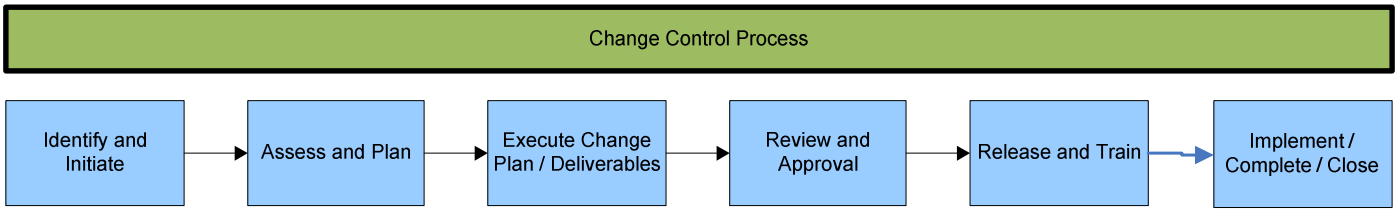
The following are allowed through the MCO process…	**CIA form**
Add attachments to existing part numbers in Agile which do not presently have all appropriate and correct attachments that were previously approved though CO process	No CIA form is required
Provide the Functional Impact Parts Worksheet for a part that was previously released without identification	No CIA form is required
Revise or delete information existing on the manufacturers tab in Agile, which will not affect AMO's ability to purchase items as long as form, fit or function is not affected Information must align with SCD.	No CIA form is required
Administrative changes to documents such as typographical error* corrections, formatting corrections,	No CIA form is required.

*Refer to definitions above.	
Administrative changes such as Item Master field value changes identify LMS field, RoHS compliant field changes, UOM, Material Type, material group, etc.,	No CIA form is required
Updates to previously approved CRs, such as changes to CIA due to expansion of CRs scope, approval requirements would be equivalent to CR approvals	No CIA form is required
Update to effectivity date of an item released through a CO	No CIA form is required.
Update/Change the Agile Lifecycle Phase of the product	CIA form is required

5.2.7 **Temporary Change Order (TCO)** is used to propose and document approval for a temporary departure from the current process/procedure.

- The TCO must include information justifying why the change is temporary rather than permanent. All considerations that need to be addressed for a Change Order are still applicable to a TCO.
- Effectivity of TCO is defined either by the affected equipment serial numbers, lot, and quantity of parts and/or a specified period of time. TCOs are not to exceed 120 days. Effectivity dates do not apply if serial or lot numbers are specified.

5.3 Process / Structure Diagram:



5.4 Essential Elements:

5.4.1 Pre-Market Change

ITEM Number	Instructions & Explanations	Forms	Reference Procedures	Responsible Party
ITEM 1 **Identify / Initiate**	This phase includes the identification of a change and the initiation of its change impact assessment. **Input:** • Understand impact to products & processes, and "Where used". Ensure the change is feasible. • Understand the benefits or justifications for change. **Activities:** 1.1 Identify/Initiate the change associated with design and development project/program. 1.2 Review or fill out the Design Project Plan Deliverables (DDP) Form to outline the deliverables for the project/ program (for Change Requests) and Change Impact Assessment form (for Change Orders) with the exception of changes related to release of Quality System procedures and MCOs identified in section 5.2.6, skip to section 1.3. Key elements: • Select Life Cycle: "New Product" • Change Description • Reason for Change, and Justification for change • Product/Line(s) Affected • Where Used 1.3 Determine if change is due to nonconformance/ product deficiency/ CAPA correction/corrective action/ Risk Evaluation • If YES, reference the applicable ER (Exception Report) or HHE (Health Hazard Evaluation) number in the Change Impact Assessment 1.4 Determine next steps: Pre-Defined Low Impact Change **IF** / **Then…** The type of change is on the list of Pre-Defined Low Impact Change. → • Change requires a Change Order (CO, MCO) • Change is Category 2 change. • Submit Change to Change Analyst to review proposed change. Include elements identified on CIA form or DDP Form during preparation of the CO. (If CO review identifies a need for review by Change Control Board (CCB), it will be scheduled for review of	*EQP-08-F100, Design Project Plan Deliverables Form*	*AMO-05-003, Change Control* *EQP-08-S100, Medical Equipment Lifecycle Management Procedure.* *EQP-03-S003, CAPA Review Board* *MIL-05-S003, Change Control Board* *MIL-05-S014, Pre-Defined Low Impact for Changes* *MIL-05-G004, Change Creation Guideline* *SOP601010,*	*Change Initiator* *R&D Engineer* *Quality Engineer* *CCB (Quality, Independent Reviewer, etc)*

ITEM Number	Instructions & Explanations	Forms	Reference Procedures	Responsible Party
			R&D Translation Process	
			SOP501111, Supplemental Material Master Information	
		FDC01544, Material Master Form		

	the proposed change.)

The change is **NOT** on the list of Pre-Defined Low Impact Change.	• Complete Section (1) of DDP or Change Impact Assessment (CIA) Form consulting with a QE, as needed :
	  • If multiple COs are required to complete release/changes , CR is required
	  • Pre-Market changes can be Change Category 1 or 2, depending upon change and its impact to released parts
	• Send documents to Change Control Coordinator Inbox (email) to schedule time with CCB to review proposed change.

The change is **to release or revise a released** Product/Catalog item number.	• Complete Section(1) of CIA Form with a QE (and RA) to determine UDI information for release or revision, when appropriate. • Complete or Revise Material Master Form, consulting with appropriate parties for information as indicated in MMF Procedure. • Attach completed or updated MMF form to Change order.

1.5 CCB will review Design Project Plan Deliverables Form or Change Impact Assessment form, when applicable, and confirm whether proposed changes are adequate and Change Category is identified correctly.

1.6 If applicable, CCB will work with initiator to identify an appropriate independent technical reviewer.

1.7 Determine the Design Verification and/or Design Validation requirements.

Output:

The following are the outputs from this phase:

- Identified the change and described change
- Determined if change requires Change Request (CR) or Change Order (CO, MCO).
- Identify if proposed change is acceptable and it does not adversely impact product design/product quality or

ITEM Number	Instructions & Explanations	Forms	Reference Procedures	Responsible Party
	processes. • Appropriate independent technical reviewer identified for future review and approval ▪ Determined the Design Verification and/or Design Validation requirements in Change Plan Task/ Action Item.			
ITEM 2 **Assess & Plan**	This phase is to perform change impact assessment for all changes that require a Change Request. In doing so, plan the appropriate change plan deliverables/action item(s) to justify and prepare for the change. A Design Project Plan Deliverables /Action Item or Change Plan task or deliverable is objective evidence for activities identified as necessary to support the design and development of a new product or release of a change to pre-market product. All Plan Deliverables/Action Item tasks must be completed prior to new product launch/change implementation into the production environment. **Input:** • Change identified to require a Design Project Plan Deliverables (DDP) Form or Change Request. **Activities:** 2.1 Change Initiator will complete Design Project Plan Deliverables (DDP) Form with Quality's guidance. 2.2 Key elements of all Change Impact Assessments 2.2.1 Regulatory Assessment 2.2.2 Design Input Assessment 2.2.3 Design Output Assessment, including procedures and processes 2.2.4 Risk Management Assessment 2.2.5 Design Verification and/or Design Validation Assessment 2.2.6 Quality System assessment, including impact to quality system documents. 2.2.7 Tasks and action item(s) identified to address design(s)/document(s) impacted, or to provide justification of no impact. These actions become the Design Project Plan Deliverables/Change Plan which must be completed to close the Change Request. 2.3 Send completed Design Project Plan Form to Change Control Coordinator Inbox (email) to schedule a meeting with CCB for review and pre-approval. **Output:** Documentation that supports**:** • Completed and pre-approved DDP and/or Change Impact Assessment Form. Identified the Plan Deliverables/Action Item or Change Plan Tasks and	*EQP-08-F100, Design Project Plan Deliverables Form*	*AMO-05-003, Change Control* *MIL-05-S003, Change Control Board* *EQP-08-S100, Medical Equipment Lifecycle Management Procedure.* *MIL-05-G004, Change Creation Guideline*	*Change Initiator* *R&D Engineer* *Quality Engineer* *CCB (Quality, Independent Reviewer, etc)* *Regulatory/ EHS*

ITEM Number	Instructions & Explanations	Forms	Reference Procedures	Responsible Party
	Action item(s), respectively. • Problem Description (Description of change) • Change Request • Proposed Actions (including acceptable Justification) • Verification and/or Validation requirements in Change Plan Task/ Action Item (if required)			
ITEM 3 **Execute**	In this phase, the initial Change Request (CR) or Change Order (CO) is initiated/submitted and change tasks/action item(s) are completed. **Input:** • Decision to create CR or CO in Agile. • Change Impact Assessment with Change Plan Task(s)/ Action item(s) outlined. **Activities:** **Change Request (CR)**: 3.1 Initiate a CR in Agile (refer to Change Creation Guideline) and, if applicable, execute Change Plan Task/Action Item identified in Design Project Plan (DDP) Form. See Steps 3.5 & 3.6. 3.2 Evaluate and update Design Project Plan Deliverables Form (DDP) or Change Impact Assessment Form and CO/CR section with QA as necessary throughout change implementation. Consult with CCB members when Change Impact Assessment requires changes. 3.3 Once all tasks are completed as outlined in the Change Impact Assessment, continue to **Item 4** with completed CR and all action item(s). **Change Order (CO):** 3.4 Create CO(s) in Agile. Refer to Change Creation Guideline 3.4.1 Identify affected document(s) or item(s), impact of change, change description, reason for change and justification for change. Include appropriate documentation or references to such documentation to support justification. 3.4.2 Prepare and attach elements necessary to create and/or update drawing or document, include CIA form, when applicable. a) Redline existing drawing/ document and outline differences in document. b) List documents that are changing and documents which require a coordinated release c) Training assessment - Items requiring training are evaluated to determine appropriate training audience or change to training audience. Evidence is to be attached to CO. d) Include all related documentation as	*Agile – Change Order/Change Request* *EQP-08-F100, Design Project Plan Deliverables Form* *or* *EQP-08-F181, Change Impact Assessment Form* *MIL-02-F002, Training Plan / Update Request Form* *MIL-05-F041, Equipment Manufacturing Change Request Closure Checklist* *EQP-14-F001, Device Labeling Change Checklist*	*MIL-05-G004, Change Creation Guideline* *SOP601010, R&D Translation Process*	*Change Initiator* *R&D Engineer* *Quality Engineer* *CCB (Quality, Independent Reviewer, etc)* *Training Coordinator/ Training Plan Owner*

ITEM Number	Instructions & Explanations	Forms	Reference Procedures	Responsible Party
	appropriate 3.4.3 For CO-associated CR, reference/link CO to CR. 3.4.4 Once CO tasks are completed, COs are routed and released according to **Item 4**. 3.5 **CO(s) associated to Protocols and Reports submission** 3.5.1 If change execution requires verification(s) or validation(s), protocols must be approved in Agile prior to implementation. Prior to submission, VRB review may be necessary. 3.5.2 Create CO(s) in Agile. Refer to Change Creation Guideline. 3.5.3 Link CO to CR (when applicable) 3.5.4 Once CO tasks are completed, COs are routed and released according to **Item 4**. 3.6 **CO(s) associated to New Part Creation (Pilot or Production lifecycle) submission** 3.6.1 Change requires verification(s) or validation(s) approved prior to implementation into product (e.g. production released assemblies). Prior to submission, VRB review may be necessary. 3.6.2 New part is an orderable, catalog level or top-level assembly, or accessory and is identified as Product type, completion of Material Master Form (MMF) and MMF Item is required. 3.7 **CO(s) associated with Device Labeling submission** 3.7.1 Change requires completion of Device Label Change Checklist in addition to the Change Impact Assessment form ©. 3.8 If a Pre-Approved Change Plan Task/Action Item, CR and/or CO are cancelled 3.8.1 Close CR and/or CO with a documented explanation. 3.8.2 Assess & document completed activities. An assessment of any related COs is necessary before cancellation of CR/CO. 3.8.3 Obtain approval from CCB. **Output:** • Initiated and Completed Change Order(s) (COs, MCOs,) in Agile. • Initiated and Completed Change Request in Agile.	*FDC01544, Material Master Form*	*SOP501111, Supplemental Material Master Information*	
ITEM 4 **Review & Approve**	This phase includes Change approval by CCB, review/approval of CR, CO, or MCO (including but not limited to submitted updated/created drawing/document to Document Control for implementation). **Inputs:** • COs are created, either as a Category 1 or Category 2 Change or as outlined in the DPP or Impact Assessment Form. Or	*Agile – Change Order/Change Request* *MIL-05-F003, Change Control Review Meeting Attendance*	*AMO-05-003, Change Control* *MIL-05-D004, Change Control Approver Matrix*	*Change Initiator* *R&D Engineer* *Quality Engineer*

<table>
<tr><th>ITEM Number</th><th>Instructions & Explanations</th><th>Forms</th><th>Reference Procedures</th><th>Responsible Party</th></tr>
<tr>
<td></td>
<td>
• All tasks for a CR are complete.
<u>Activities:</u>
4.1 Change Initiator will work with Change Control Board to ensure the appropriate quality engineer and independent reviewer and individual/ functional area to be notified are listed in the Agile Change Order/Workflow.
<table>
<tr><th>Approver/ Notification Matrix</th><th>CR, CO, MCO</th><th>TCO</th></tr>
<tr><td><u>MIL-05-D004</u>
<u>Pre-Market Changes worksheet</u>
(i.e.: New Product/ Design Project):
Development
or
Pilot Life cycle</td><td>See
MIL-05-D004
If, CR or CO identified Regulatory Impact in Section of the CIA, Regulatory approval is required.</td><td>N/A</td></tr>
</table>
4.2 Initiator requests a meeting with CCB (with exception of Low Impact changes) to review the CO or the completed CR (and all associated COs and other action item(s)).
4.2.1 CRs are closed according to CR Closure process section.
4.3 CCB will review a Change Order (e.g. CR, CO, MCO) for completeness and accuracy
4.3.1 Change, Reason, and Justification for the acceptability of the changes are present, clear and concise
4.3.2 Potential impact of changes is addressed and justified
4.3.3 Identification of training needs, when applicable
4.3.4 Correct approvers and functional areas to be notified are identified.
4.3.5 Required forms and attached documents are completed.
4.3.6 ‘Where Used’ is completed and accurate.
4.3.7 Timeframe for implementation is present (effectivity date)
4.3.8 Correct document(s) are attached
4.3.9 Attached document(s) are technically correct
4.4 CCB will confirm all Change Plan Tasks/Action item(s) have been completed and are accurate for a CR or CO.
</td>
<td></td>
<td>MIL-05-S003, Change Control Board

MIL-05-S014, Pre-Defined Low Impacts

MIL-05-G004, Change Creation Guideline

SOP501110, Agile Effectivity Date Guidelines</td>
<td>CCB (Quality, Independent Reviewer, etc)

Regulatory

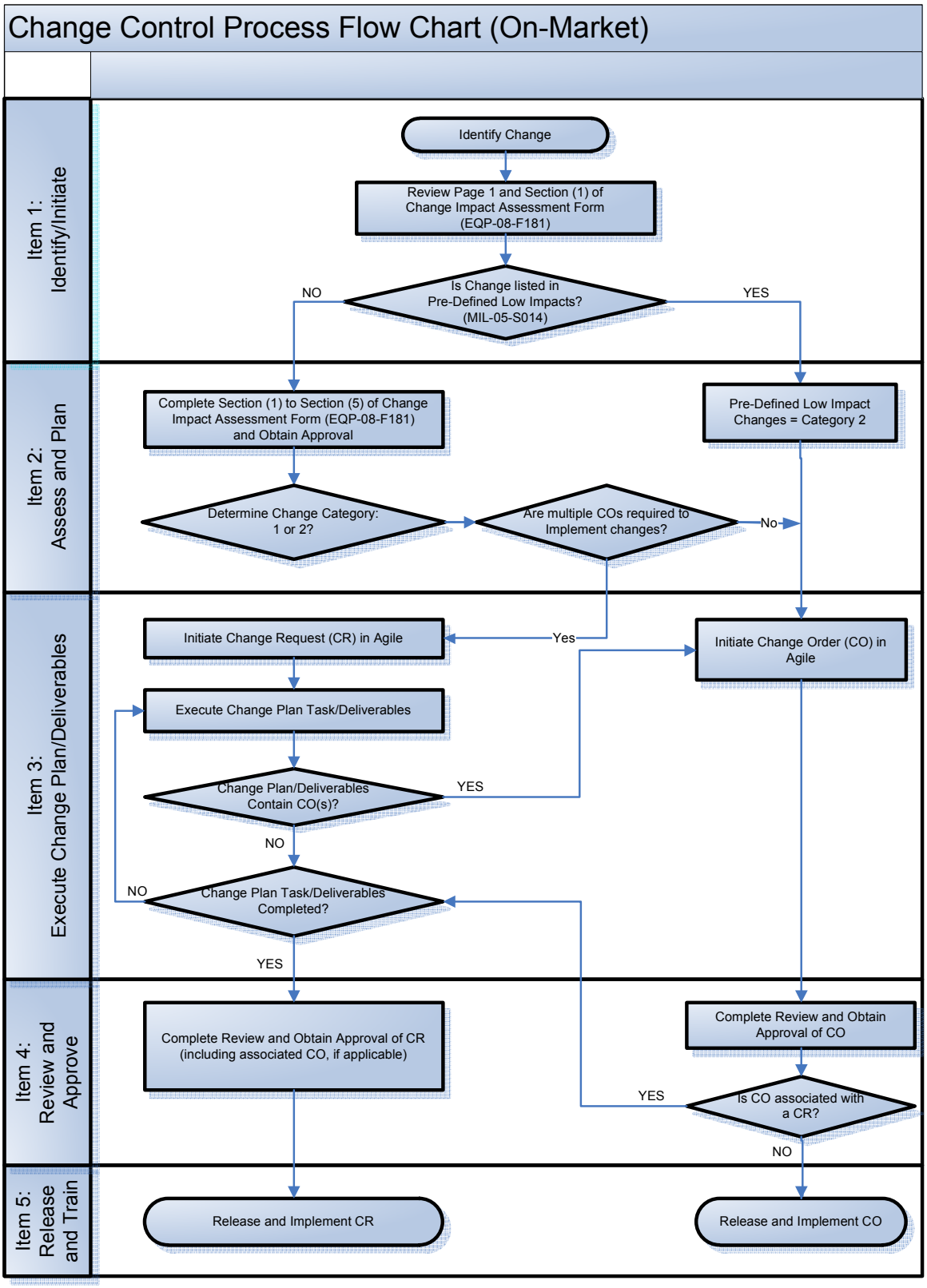
Change Analyst</td>
</tr>
</table>

ITEM Number	Instructions & Explanations	Forms	Reference Procedures	Responsible Party
	4.5 Document Control will submit updated/new documents to Approval Status. 4.6 Approvers approve the Change Order or Change Request (CR) in Agile. 4.7 Changes must be approved by CCB members (and/or functions indicated in Approval Matrix) and the Change Initiator (i.e. Change Initiator's approval is represented through agreement and submission of Change). 4.8 If the approved Change Order is associated with an incomplete CR/Change Plan, continue with the rest of the Change Plan in **Item 3**. **Output:** • Change Orders/Requests issued to Approval Status. • Change and Change plan Tasks/Action item(s) are reviewed and Change is approved. • Change (e.g. CR, CO, MCO) is reviewed and approved).			
ITEM 5 Release /Train	This phase is to implement the change and release CR, CO, or MCO. **Input:** • Approved CR, CO(s) or MCO. **Activities:** 5.1 Upon CCB or approval and notification of specified functional areas, the change analyst will review history and workflow to ensure comments documented by the approvers are addressed, coordinates the document update, review, release and implementation of the change. 5.2 Change Analysts release 5.2.1 COs: Change Orders to Released/ Implemented Status. Lifecycle and effectivity of Parts/Documents is then updated as appropriate according to approved CO/MCO. • For items that require training, an effectivity date including up to 30 (working) days is set • For Changes releasing product-related software, a Software/CD master is supplied by the Originator to Document Control for archival and duplication purposes. 5.2.2 CRs: Change Analysts notify Originators of CR being fully approved. • The CR remains at the Approval stage. CR moves to Released status when approved CR activities are completed. • Lifecycle, revisions and effectivity of parts/documents is updated through CO or MCO process. The Affected Items will "flag" an Originator of the approved CR when item is placed into a Change Order (CO/MCO/CR).	*Agile Change Request / Change Order* *MIL-02-F002, Training Plan / Update Request Form*	*MIL-05-G104, Change Order Disposition Implementation* *MIL-02-S002, Personnel Training and Records Management* *MIL-05-S001, Document and Data Control Requirements*	*Change Initiator* *R&D Engineer* *Quality Engineer* *Training Coordinator/ Training Plan Owner* *Change Analyst*

ITEM Number	Instructions & Explanations	Forms	Reference Procedures	Responsible Party
	5.3 Training and supporting documented evidence are completed according to training requirements. 5.4 Change Analysts notify functional areas and originators in order for them to fulfill their responsibilities: • Adding or removing controls preventing use in production/product • Material disposition – including completion of any rework activities • Move DMR into status appropriate for lifecycle of product/part; provide an effective date to DHF records. • Release and Closure of Approved CRs based upon completed COs or executed activities. • SAP transfer is reviewed and required MMF entries are completed for Product type (FERT) items using information from the MMF. 5.5 Distribution of documents - Follow document control procedures to ensure distribution and handling of approved redlines is appropriate. 5.6 If item being released is a procedure or requires a particular effective date, the change will be released and implemented by setting an effective date of the document and a training window (*Scheduled For*...lifecycle) on the Affected Items tab. 5.7 Upon release of the CO, the new revision (or clean copy) of the document or drawing will be attached to the item master attachments tab. Lifecycle and effectivity of Parts/Documents is then updated as appropriate according to approved CO/MCO. 5.8 No changes should be made to the CO once a Change is implemented, with the exception of the following: • Records of training completion are added at the Released stage (when applicable) as attachments. • Changes accepted and approved through the use of an MCO and approved by Quality. **Output:** The following are examples of outputs from this phase: • Documentation that training is complete. • Approved CR; Implemented MCO or CO(s). • Issued Document/Drawing/DHF records to production status and updated material disposition.			

5.4.2 On-Market Change

Process/Structure Diagram



<table>
<tr><th>ITEM Number</th><th>Instructions & Explanations</th><th>Forms</th><th>Reference Procedures</th><th>Responsible Party</th></tr>
<tr>
<td>ITEM 1
Identify / Initiate</td>
<td>
This phase includes the identification of a change and the initiation of its change impact assessment.

<u>Input:</u>

• Understand impact to products & processes, and “Where used”. Ensure the change is feasible.
• Understand the benefits or justifications for change.

<u>Activities:</u>

1.1 Identify the change.
1.2 Review or fill out the Change Impact Assessment (CIA) form with the exception of changes or the release of Quality System procedures and MCOs identified in section 5.2.6, skip to section 1.3. Key elements:
• Select Life Cycle: On-Market
• Change Description
• Reason for Change, and Justification for change
• Product/Line(s) Affected
• Where Used
1.3 Determine if change is due to nonconformance/product deficiency/ CAPA correction action/ Risk Evaluation
• If YES, reference the applicable ER (Exception Report) or HHE (Health Hazard Evaluation) number in the Change Impact Assessment
• If YES and there is no documented ER or HHE, escalate to the CAPA Review Board
1.4 Determine next steps: Pre-Defined Low Impact Change
<table>
<tr><th>IF</th><th>Then…</th></tr>
<tr><td>The change is on the list of Pre-Defined Low Impact Change.</td><td>• Change requires a Change Order (CO, MCO)
• Change is a Category 2.
• Submit Change to Change Analyst to review proposed change. Include elements identified on CIA form during preparation of the CO. (If CO review identifies a need for review by Change Control Board (CCB), it will be scheduled for review of the proposed change.</td></tr>
<tr><td>The change is NOT on the list of Pre-Defined Low Impact Change.</td><td>• Complete Section (1) of Change Impact Assessment (CIA) Form with a QE to determine the Change</td></tr>
</table>
</td>
<td>EQP-08-F181, Change Impact Assessment</td>
<td>MIL-05-S003, Change Control Board

MIL-05-S014, Pre-Defined Low Impact for Changes

MIL-05-G004, Change Creation Guideline

EQP-09-S600, Verification Process

EQP-03-S003, CAPA Review Board

EQP-09-S001, Validation Overview</td>
<td>Change Initiator

R&D Engineer

Quality Engineer

CCB (Quality, Independent Reviewer, etc)</td>
</tr>
</table>

ITEM Number	Instructions & Explanations		Forms	Reference Procedures	Responsible Party
		Category: • If multiple COs are required to complete release/changes, CR is required. • Determine Change Category 1 or 2, depending upon change and its impact to released parts. (Refer to Terminology section for Form, Fit or Function definition and Appendix A.) • Send documents to Change Control Coordinator Inbox (email) to schedule time with CCB to review proposed change.	*EQP-09-F001, Validation Review Board Meeting Attendance Record*	*EQP-08-S186, Change Impact Assessment Process*	
	The change is **to release or revise a released** Manufacturing Instruction or Test Method.(C)	• Complete Section (1) of CIA Form with a Quality representative to determine the Change Category: • Determine Change Category 1 or 2, depending upon change and its impact to released process. • Determine whether "Yes" was checked within Section Verification/Validation and Qualification section of the CIA. • If "Yes" was checked, ensure the VRB attendance sheet is attached to the CO as appropriate for the item © • Send documents to Change Control Coordinator Inbox (email) to schedule time with CCB to review proposed change.			
	The change is to **release or revise a released** Product/Catalog/Registered item number	• Complete Section(1) of CIA Form with a QE (and RA) to determine UDI information for release or revision. • Complete or Revise Material Master Form, consulting with appropriate parties for information as indicated in MMF Procedure.	*FDC01544, Material Master Form*	*SOP501111, Supplemental Material Master Information*	

ITEM Number	Instructions & Explanations	Forms	Reference Procedures	Responsible Party
	<table><tr><td></td><td>• Attach completed or updated MMF form to Change order.</td></tr><tr><td>The change is to an **item/part purchased from an OEM or TPM**</td><td>• Complete Initial Page of CIA, as well as Section (1) if item is not part of PDLI Listing. • Include the purchased level assembly as an Affected Item on the CIA and the CO to ensure any changes that impact the assembly are communicated and implemented by the OEM or TPM.</td></tr></table> 1.5 CCB will review Change Impact Assessment form and confirm whether proposed changes are adequate and Change Category is identified correctly. 1.6 If applicable, CCB will work with initiator to identify an appropriate independent technical reviewer. 1.7 Determine the Verification and/or Validation requirements. Validation is required IF: • Design Changes impact Product – a change that affects physical characteristics (form, fit, function) intended for use by customers or field service • Design Changes impact Process – a change that affects Abbott manufacturing processes, equipment, or tools used by manufacturing only. • Design Changes impact Process – a change that affect fit, form, function, safety or efficacy of the product • Design Changes impact Validation (i.e.: Facilities, Utilities, Equipment (FUE), Test Method, or Process. **Output:** Documentation that supports • Description of change • Change type (i.e. Change Request (CR) or Change Order (CO, MCO, or TCO). • Acceptable Justification, Name (and signature) of appropriate independent technical reviewer. • If Verification and/or Validation requirements in Change Plan Task/ Action Item.	*EQP-08-F181, Change Impact Assessment*		
ITEM 2 **Assess & Plan**	This phase is to perform change impact assessment for all changes that require a Change Order or Change Request. In doing so, plan the appropriate change plan tasks/action item(s) to justify and prepare for the change.	*EQP-08-F181, Change Impact Assessment Form*	*AMO-05-0003, Change Control*	*Change Initiator* *R&D Engineer*

ITEM Number	Instructions & Explanations	Forms	Reference Procedures	Responsible Party
	A Change Plan task or deliverable is objective evidence for an activity identified as necessary to support the development of a new part/product or release of a change to an on market product. All tasks must be completed prior to new part introduction/product launch/change implementation into the production environment. **Input:** • Change identified to require a Change Request or Change Order. **Activities:** 2.1 Change Initiator will complete Change Impact Assessment with Quality's guidance. 2.1.1 Key elements of all Change Impact Assessments 2.1.2 Regulatory Assessment. RA representative is to be contacted / consulted to assist in completion of this subsection. 2.1.3 Design Input Assessment 2.1.4 Design Output Assessment, including procedures and processes 2.1.5 Risk Management Assessment 2.1.6 Verification and/or Validation requirements Assessment 2.1.7 Quality System assessment, including impact to quality system documents and records 2.1.8 Tasks and action item(s) identified to address design(s)/document(s) impacted, or to provide justification of no impact. These actions become the Change Plan which must be completed to close the Change Request. 2.2 Send completed Change Impact Assessment form (when applicable) to Change Control Coordinator Inbox (email) to schedule a meeting with CCB for review and pre-approval. **Output:** • Completed and pre-approved Change Impact Assessment. Identified Change Plan Tasks and Action item(s).		*MIL-05-S003, Change Control Board* *EQP-08-S100, Medical Equipment Lifecycle Management Procedure* *MIL-05-G004, Change Creation Guideline*	*Quality Engineer* *CCB (Quality, Independent Reviewer, etc)* *Regulatory/ EHS*
ITEM 3 Execute	In this phase, the initial Change Request (CR) or Change Order (CO) is initiated and change tasks/action item(s) are completed. **Input:** • Decision to create CR or CO in Agile. • Change Impact Assessment with Change Plan Task(s)/ Action item(s) outlined.	*Agile – Change Order/Change Request* *EQP-08-F181, Change Impact Assessment*	*MIL-05-G004, Change Creation Guideline* *SOP601010, R&D Translation Process*	*Change Initiator* *R&D Engineer* *Quality Engineer*

ITEM Number	Instructions & Explanations	Forms	Reference Procedures	Responsible Party
	Activities: **Change Request (CR):** • Initiate a CR in Agile (refer to Change Creation Guideline), and, if applicable, execute Change Plan Task/Action Item identified in Change Impact Assessment Form. See Steps 3.5 & 3.6. • Evaluate and update Change Impact Assessment Form with QA as necessary throughout change implementation. Consult with CCB members when Change Impact Assessment requires changes. • Once all tasks are completed as outlined in the Change Impact Assessment, continue to **Item 4** with completed CR and all action item(s). **Change Order (CO)/MCO:** • Create CO(s)/MCO(s) in Agile. Refer to Change Creation Guideline o Identify affected document(s) or item(s), impact of change, change description, reason for change and justification for change. Include appropriate documentation or references to such documentation to support justification. o Identify assessment of change to OEM or TPM purchased level parts. o Prepare and attach elements necessary to create and/or update drawing or document, including rework instructions (when applicable) o Include CIA form, when applicable. o Include all related documentation as appropriate. o Redline existing drawing/ document and outline differences in document. ▪ Revisions to documents completed as part of corrective action are to be indicated with the mark "©" directly adjacent to the addition. This mark is to remain as part of the new revision/cleancopy. o List documents that are changing and documents which require a coordinated release o If CO is associated to a CR, link to CR. o If CO/MCO is associated to a CAPA, link to CAPA. o Training assessment - Items requiring training are evaluated to determine	*Form* *MIL-02-F002, Training Plan / Update Request Form* *MIL-05-F041, Change Request Closure Checklist* *EQP-14-F001, Device Labeling Change Checklist* *FDC01544, Material Master Form*	*MIL-05-G403, Redline/Marked Revision Creation Guideline*	*CCB (Quality, Independent Reviewer, etc)* *Training Coordinator/ Training Plan Owner*

ITEM Number	Instructions & Explanations	Forms	Reference Procedures	Responsible Party
	appropriate training audience or change to training audience. Evidence is to be attached to CO. ▪ For training plans and procedures, determine appropriate implementation plan or effectivity date. Include implementation plan in the procedure or as part of the CO cover page (e.g. add information to Description Change Details section of the CO cover page). © ▪ Once CO tasks are completed, COs are routed and released according to **Item 4**. o **CO(s) associated to Protocols and Reports submission** ▪ If change execution requires verification(s) or validation(s), protocols must be approved in Agile prior to implementation. VRB review prior to submission may be necessary. ▪ Create CO(s) in Agile. Refer to Change Creation Guideline. ▪ Reference/link CO to CR (when applicable) ▪ Once CO tasks are completed, COs are routed/released according to **Item 4**. o **CO(s) associated to New Part Creation (Pilot or Production lifecycle) submission** ▪ Change requires verification(s) or validation(s) approved in Agile prior to implementation into product (e.g. production released assemblies) ▪ New part is an orderable, catalog level or top-level assembly or accessory and is identified as Product type (FERT), requires completion of Material Master Form (MMF). • MMF Item is to be created. o **CO(s) associated with Device Labeling submission** ▪ Change requires completion of Device Label Change Checklist in addition to the Change Impact Assessment form ©. o If a Pre-Approved Change Plan Task/Action Item, CR and/or CO are cancelled – close CR and/or CO with a documented explanation. Assess & document completed activities. An assessment of any related COs is necessary before cancellation of CR/CO o **CO(s) associated to Quality System document creation or revision**		*EQP-05-S002 Quality System Documentation Structure and Contents*	

<table>
<tr><th>ITEM Number</th><th>Instructions & Explanations</th><th>Forms</th><th>Reference Procedures</th><th>Responsible Party</th></tr>
<tr><td></td><td>submission
If CO is releasing a new quality system document that requires training, the training plan is to be updated at the same time or immediately thereafter (Change number is to be referenced)
New quality system procedures are to be added to the appropriate subsystem index at the time of their release.
Quality system procedure revisions are to be assessed for impact of changes to associated guidelines, forms, templates or indices as well as Divisional policies (when applicable). Assessment of these changes is to be documented within Change Order.
<u>Output:</u>
Obtain approval from CCB / approvers.
Initiated and Completed Change Order(s) (COs, MCOs, or TCOs) in Agile.
Initiated and Completed Change Request in Agile.</td><td></td><td></td><td></td></tr>
<tr><td>ITEM 4

Review & Approve</td><td>This phase includes Change approval by CCB, review/approval of CR, CO, MCO, or TCO (including but not limited to submitted updated/created drawing/document to Document Control for implementation).

<u>Inputs:</u>
COs are created, either as a Category 1 or 2 Change or as outlined in the Impact Assessment Form.

Or
Tasks identified to support changes proposed in CR are complete.
<u>Activities:</u>

4.1 Change Initiator will work with Change Control Board to ensure the appropriate quality representative, independent reviewer (product changes) and individual/ functional area to be notified are listed in the Agile Change Order/Workflow.

<table><tr><th>Approver/ Notification Matrix</th><th>CR, CO, MCO</th><th>TCO</th></tr><tr><td><u>MIL-05-D004</u>
<u>On-Market Changes worksheet</u>
Production or Obsolete
Life cycle</td><td>Refer to MIL-05-D004 - On-Market Changes Worksheet or QS and Business Practices
If the Change identified</td><td>Refer to MIL-05-D004 - On Market Changes Worksheet

Equipment Site’s Quality</td></tr></table></td><td>MIL-05-F003, Change Control Review Meeting Attendance

EQP-08-F181, Change Impact Assessment Form</td><td>AMO-05-003, Change Control

MIL-05-D004, Change Control Approver Matrix

MIL-05-S003, Change Control Board

MIL-05-G004, Change Creation Guideline

SOP501110, Agile Effectivity Date Guidelines</td><td>Change Initiator

R&D Engineer

Quality Engineer

CCB (Quality, Independent Reviewer, etc)

Regulatory

Change Analyst</td></tr>
</table>

ITEM Number	Instructions & Explanations	Forms	Reference Procedures	Responsible Party

	Regulatory impact in Section 1 of the CIA, Regulatory approval is required.	Director approval is required.

4.2 Initiator requests a meeting with CCB (when required) to review the CO or the completed CR (and all associated COs and other action item(s)). If change only impacts Quality System documents, initiator will schedule a meeting with Quality CCB (QS-CCB).

4.2.1 CRs are closed according to CR Closure process section.

4.3 CCB will review a Change Order (CR, CO, MCO, TCO) for completeness and accuracy

4.3.1 Change, Reason, and Justification for the acceptability of the changes are present, clear and concise

4.3.2 Potential impact of changes is addressed

4.3.3 Identification of training needs, when applicable

4.3.4 Correct approvers and functional areas to be notified are identified.

4.3.5 Required forms and attached documents are completed

4.3.6 'Where Used' is completed and accurate.

4.3.7 Timeframe for implementation (effectivity date)

4.3.8 Correct document(s) are attached

4.3.9 Attached document(s) are technically correct

4.4 CCB will confirm all Change Plan Tasks/Action item(s) have been completed and are accurate for a CR or CO.

4.5 Document Control will submit updated/new documents to Approval Status.

4.6 Approvers can then approve the Change Order (CO, MCO, TCO) or Change Request (CR) in Agile.

4.7 Changes must be approved by CCB members (and/or functions indicated in Approval Matrix) and the Change Initiator (i.e. Change Initiator's approval is represented through agreement and submission of Change).

4.8 If the approved Change Order is associated with an incomplete CR/Change Plan, continue with the rest of the Change Plan in **Item 3**.

Output:

- CO, CR, MCO or TCO is reviewed and approved.
- Change plan Tasks/Action item(s) are reviewed and

ITEM Number	Instructions & Explanations	Forms	Reference Procedures	Responsible Party
	Change Request is approved. • Change Orders/Requests issued to Approval Status.			
ITEM 5 **Release** **/Train**	This phase is to implement the change and close CO, or MCO, or TCO. **Input:** • Approved CR, MCO, TCO or CO(s). **Activities:** 5.1 Upon CCB or QS-CCB approval and notification of specified functional areas, the change analyst will review history and workflow to ensure comments documented by the approvers are addressed, coordinates the document update, review, release and implementation of the change. 5.2 Change Analysts release: 5.2.1 Change Orders to Released/ Implemented Status. Lifecycle and effectivity of Parts/Documents is then updated as appropriate according to approved CO/MCO. • For items that require training, an effectivity date including up to 30 (working) days is set. • For Changes releasing product-related software, a Software/CD master is supplied by the Originator to Document Control for archival and duplication purposes. 5.2.2 CRs: Change Analysts notify Originators of CR being fully approved. • The CR remains at the Approval stage. CR moves to Released status when approved CR activities are completed. • Lifecycle, revisions and effectivity of parts/documents is updated through CO or MCO process. The Affected Items will "flag" an Originator of the approved CR when item is placed into a Change Order (CO/MCO/CR). 5.3 Training and supporting documented evidence are completed according to site training requirements. 5.4 Change Analysts notify functional areas and Originators in order for them to fulfill their responsibilities: • Remove controls preventing use in production/product • SAP transfer is reviewed and required MMF UDI entries are completed for Product type (FERT) items using information from the MMF. • Material disposition – including completion of	*Agile Change Request / Change Order* *EQP-12-F003, Rework (Production) Instruction Form*	*MIL-05-G104, Change Order Implementation* *MIL-05-S001, Document and Data Control Procedure* *EQP-12-S011, SAP Master Data Procedure*	*Change Initiator* *R&D Engineer* *Quality Engineer* *Training Coordinator/ Training Plan Owner* *Change Analyst*

ITEM Number	Instructions & Explanations	Forms	Reference Procedures	Responsible Party
	any rework activities • Move DMR into production status; provide an effective date to DHF records. • Release and Closure of Approved CRs based upon completed COs or executed activities. 5.5 Distribution of documents - Follow document control procedures to ensure distribution and handling of approved redlines is appropriate. 5.6 If item being released is a procedure or an item that requires a particular effective date, the change will be released and implemented by setting an effective date of the document and a training window (*Scheduled For*… lifecycle) on the Affected Items tab. 5.7 Upon release of the CO, the new revision (or clean copy) of the document or drawing will be attached to the item master attachments tab. Lifecycle and effectivity of Parts/Documents is then updated as appropriate according to approved CO/MCO. 5.8 No changes should be made to the CO once a Change is implemented, with the exception of the following: • Records of training completion are added at the Released stage (when applicable) as attachments • Changes accepted and approved through the use of an MCO and approved by Quality. **Output:** The following are examples of outputs from this phase: • Completed training. • Approved CR; Implemented MCO, TCO, or CO(s). • Issued Document/Drawing/DHF records to production status and updated material disposition.			

5.4.3 Change Request (CR) Closure

5.4.3.1 Change requests are closed upon completion of:

- the activities / change plan tasks or action items proposed in the CR and CIA form are completed,
- Change Orders completing the activities/action items are implemented
- Product / Project is considered complete/released.

5.4.3.2 Originator(s), or designee, completes the:

- o Change Request Closure Checklist, MIL-05-F041 [for On-Market] or
- o Updates the approved attached CIA indication completion of actions by “versioning” the form (i.e. updates are indicated using Revision Marking and incrementing the version identified) [for On-Market] or

- Updates approved, attached EQP-08-F181 [for pre-market]

5.4.3.3 Originator, or designee, documents the proposed activities, comments and executed activities as they align with the Change Impact Assessment Form (EQP-08-F181) or Design and Deliverables Form (EQP-08-F100). No changes to Approved CIA or actions are to be done without the CR being "versioned" and re-approved by all applicable functions.

- In the event an Originator is re-assigned to another function or project or employment is terminated, it is the responsibility of the Originator's manager to reassign any open CRs to ensure activities are completed closure occurs.

5.4.3.4 The completed Closure or updated CIA or DDP form is reviewed by Quality.

5.4.3.5 The finalized copy of the form is submitted to Document Control and added to the applicable CR by the Change Analyst. The Change Analyst adds the QA and Originator, or designee, to the CR for electronic approval.

5.4.3.6 Once approval is received, the Change Analyst submits the CR to the CLOSED status.

5.4.3.7 Closed CRs are not used for Change Orders after closure date. New CRs are created, reviewed, and routed per Essential Elements above for any new Changes.

END OF DOCUMENT

Appendix A – Form, Fit or Function Assessment Table

Changes to parts would require either a revision change or a new part number according, but not limited, to the following:

If….	Then…	Change Category
A part is changed and the change is 100% Form, Fit and Function compatible.	Interchangeable, revision change.	Category 2
Item is part of equipment in the field and must be replaced because of reliability or safety reasons.	Non-interchangeable, new part number.	Category 1
Item is part of spares inventory and must be purged and/or replaced.	Non-interchangeable, new part number	Category 1
Service Level Documentation would be lost due to change.	Non-interchangeable, new part number	Category 1
A part has been altered, selected or changed in such a manner that the old and new items are not directly and completely interchangeable. See exception conditions.	Non-interchangeable, new part number.	Category 1
New part will physically fit and function in place of the old, but the old cannot be used in place of the new item. See exception conditions.	Non-interchangeable, new part number.	Category 1
Inventory management requires change and traceability (e.g. RoHS)	Non-interchangeable, new part number	Category 1
After applying the rules and guidelines specified above it is unclear	New part number	Category 1 or 2, dependent upon Change Impact Assessment

Exceptions:

Parts, if shipped, will be replaced or reworked to the new configuration, and re-identified as a new number.

The change is interchangeable at the service level, and the current parts (in-house, on order, in process) are either scrapped or reworked to the new configuration.

END OF APPENDIX