

SQP-005

Change Control

<u>Issue</u>	<u>Date</u>	<u>Details of Change</u>	<u>Changed By</u>	<u>Authorised By</u>
1	29/06/20	Initial Implementation	R. Digby	R. Digby
2	25/11/20	3.4.1.6 Added to cover distribution and flow down of updates	Dom Adams	R.Digby

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1	Shared Information Platform/Quality Centre	Robert Digby	25/11/20

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1.0 Scope and Purpose

1.1 Purpose

The purpose of this procedure is to outline the methods used by Sigma ASL to control changes throughout the organisation in relationship to the QMS.

1.2 Scope

This document will describe the tools used to track and apply changes throughout the business in relation to the following documentation.

- Drawings
- Specifications
- Procedures and work instructions
- Quality forms

2.0 Authorities and Responsibilities

It shall be the responsibility of the quality department to ensure all changes are documented, traceable and the flow down of changes including the implications of change to the relevant parties.

It shall be the responsibility of all Sigma ASL employees to inform the quality department immediately to any proposed changes listed above. Their responsibility also extends to using / referencing the most up to date versions of documentation (Where applicable).

3.0 General Information

Any changes for implementation shall have all impacts taken into consideration. These impacts can be, but shall not be limited to the following

- Costing
- Accreditation and relevant approvals for the product and premises
- Resourcing
- Lead time
- Stock and WIP

These possible impacts of change have been highlighted in the relevant swim lanes in this procedure. All the above impacts shall be communicated to the customer when firm numbers and implications have been determined. This is relevant for any areas of change or proposed change highlighted in this procedure.

3.1 Drawing issue changes

Drawing issue changes shall be carried out by the Engineering / quality department when a new revision is requested from the customer. Changes to the drawing may have a commercial impact on the business. Before using / working to a new issue the commercial impact shall be reviewed and accepted by Sigma ASL.

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Drawing issue changes shall be carried out by an authorised person as stated in the Approved Signatories List (ASL).

Drawing issue changes shall require the part to have a new contract review as per procedure SQP-003.

3.1.1 Resource

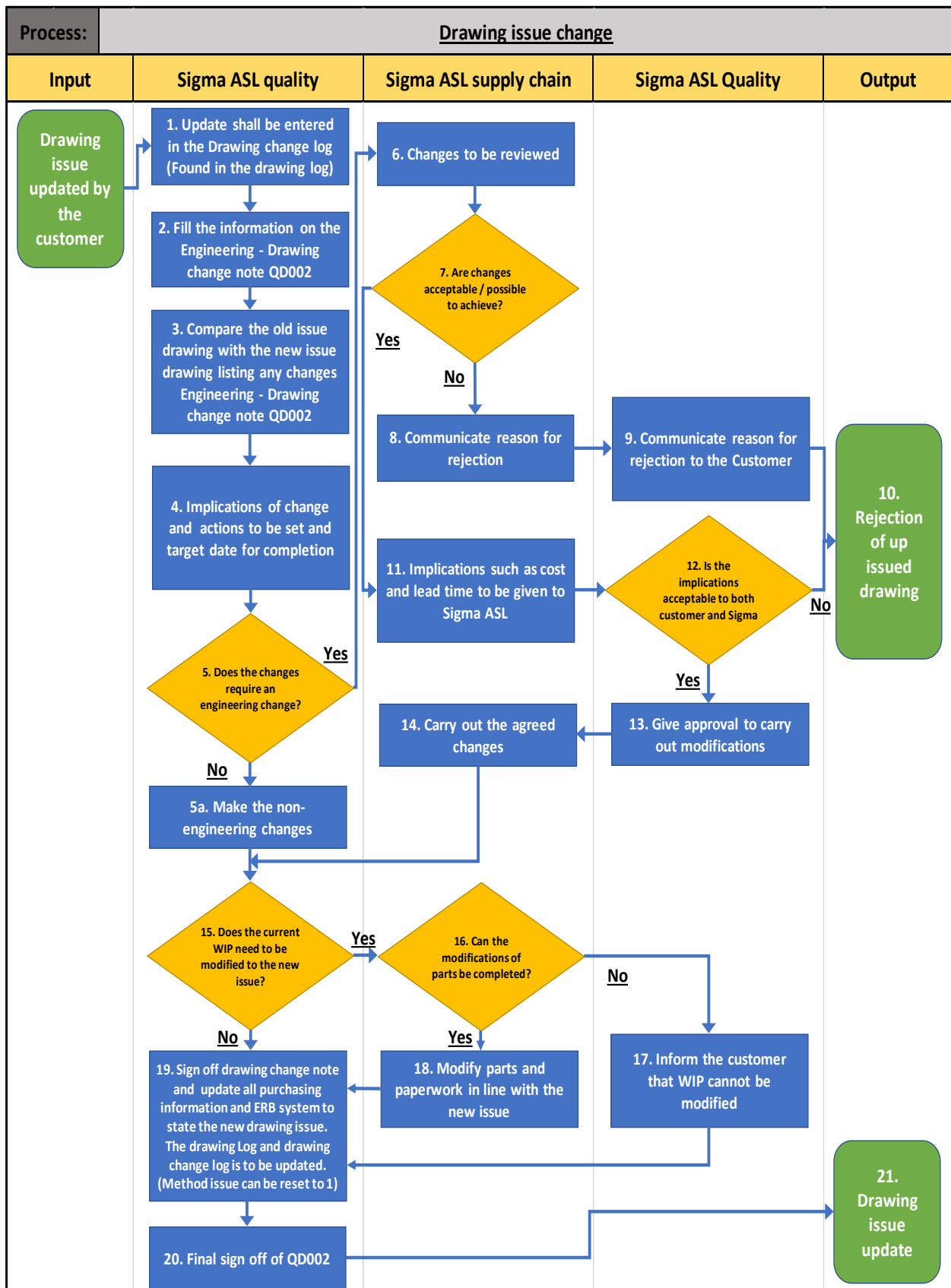
- Drawing / Engineering change note form QD002
- Drawing change log
- Drawing log

3.1.2 Notes to consider

Once the Drawing issue change has been carried out a FAIR must be completed and submitted to the customer in accordance with FAIR SQP-010

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3.1.3 Swim lane for drawing issue changes



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3.1.4 Swimlane Description

Start	Drawing issue updated by the customer	Input
	-	
1	Update shall be entered in the drawing change log	Action
	- (Found in the drawing log)	
2	Fill the information on the engineering / drawing change note	Action
	- Form number QD002	
3	Compare the old issue drawing with the new issue drawing listing any changes.	Action
	- Changes to be listed on the engineering / drawing change note QD002	
4	Implications of change and actions to be set and target date for completion	Action
	- List this information on QD002	
	Impact of proposed changes shall be considered such as, but not limited to;	
	- Costing	
	- Accreditation and relevant approvals for the product and premises	
	- Resourcing	
	- Lead time	
	- Stock and WIP	
5	Does the changes require an engineering change?	Decision
	- Engineering changes are dimensional / processing changes. Non-engineering changes can include re-draw of drawing / something that does not change the current method of manufacture.	
	- I yes move to section 6	
	- If no move to section 5A	
5A	Make the non-engineering changes	Action
	- Move to section 15	
6	Changes to be reviewed	Action
	- The supplier shall review the changes stated on the form QD002 and review the new issue drawing.	
7	Are changes acceptable / possible to achieve?	Decision
	- If yes the supplier will sign off in the relevant section on QD002 and return to Sigma ASL Quality / Engineering department. (Move to section 11)	
	- If No the supplier will enter reject onto form QD002 and sign (also see section 8.)	
8	Communicate reason for rejection	Action
	- Supplier will send the reason why they must reject the engineering change.	
9	Communicate reason for rejection to the customer	Action
	- Sigma Quality / Engineering to send reasons for rejection (QD002 and other supporting documents) to the customer	
10	Rejection of up issued drawing	Output
11	Implementations such as cost and lead time to be given to Sigma ASL	Action
	- This information will be provided as supporting documentation with QD002	
12	Is the implications acceptable to both customer and sigma ASL	Decision

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	- Both the customer and Sigma ASL quality/engineering will sign off in the relevant section of QD002 (Agreement of proposed changes) If no see section 10 if yes see section 13.	
13	Give approval to carry out modifications	Action
	- Send a signed copy of QD002 to the supplier and authorise the modifications	
14	Carry out the agreed changes	Action
	- Supplier shall make the modification agreed	
15	Does the current WIP need to be modified to the new issue?	Decision
	- Check with the customer if they will accept any current WIP to be provided to the current drawing issue or if they would like it modified to the new issued drawing	
	- If yes see section 16	
	- If no see section 19	
16	Can the modification of parts be completed?	Decision
	- Supplier will assess if WIP can be modified to the new issue	
	- If No see section 17	
	- If yes see section 18	
17	Inform the customer that WIP cannot be modified	Action
	-	
18	Modify parts and paperwork in line with the new issue	Action
	-	
19	Sign off drawing change note and update all purchasing information and ERB system to state the new drawing issue. The drawing Log and drawing change log is to be updated. (Method issue can be reset to 1)	Action
	-	
20	Final sign-off of QD002	Action
	- Sign the 'Final sign off' of QD002 including the date of implementation and store on the Network	
21	Drawing issue update complete	Output
	-	

3.2 Engineering change notes

Engineering changes shall be made when there is a change to the processes / methods of manufacture for the part. Engineering changes are to be managed out by the Engineering / quality department.

(The drawing change process in 3.1 shall be used instead of the engineering change procedure for process / manufacturing changes attributed to a drawing issue change)

Engineering change notes shall be carried out by an authorised person as stated in the ASD

3.2.1 Resource

- Drawing / Engineering change note form QD002
- Engineering change log

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3.2.2 Notes to be considered

Once the Engineering change has been carried out a Delta FAIR as per AS9102, shall be completed and submitted to the customer in accordance with FAIR SQP-010. The decision as to whether a FAIR is required shall fall with the Quality Department who shall check the customer's specifications and contact the customer to discuss the requirement if necessary.

Changes that affect other processes within Sigma ASL shall be noted within Engineering Change Note QD002. Once reviewed and acknowledged by the department the representative shall sign and date next to the action.

3.2.2 Definition of Engineering changes

The definition for an engineering change shall consist of the following but customer specific requirements are as per SQP-005 Appendix A;

- Change / modifications to the defined process agreed upon by the part FAIR.
- Change of supply source for processes / manufacture.

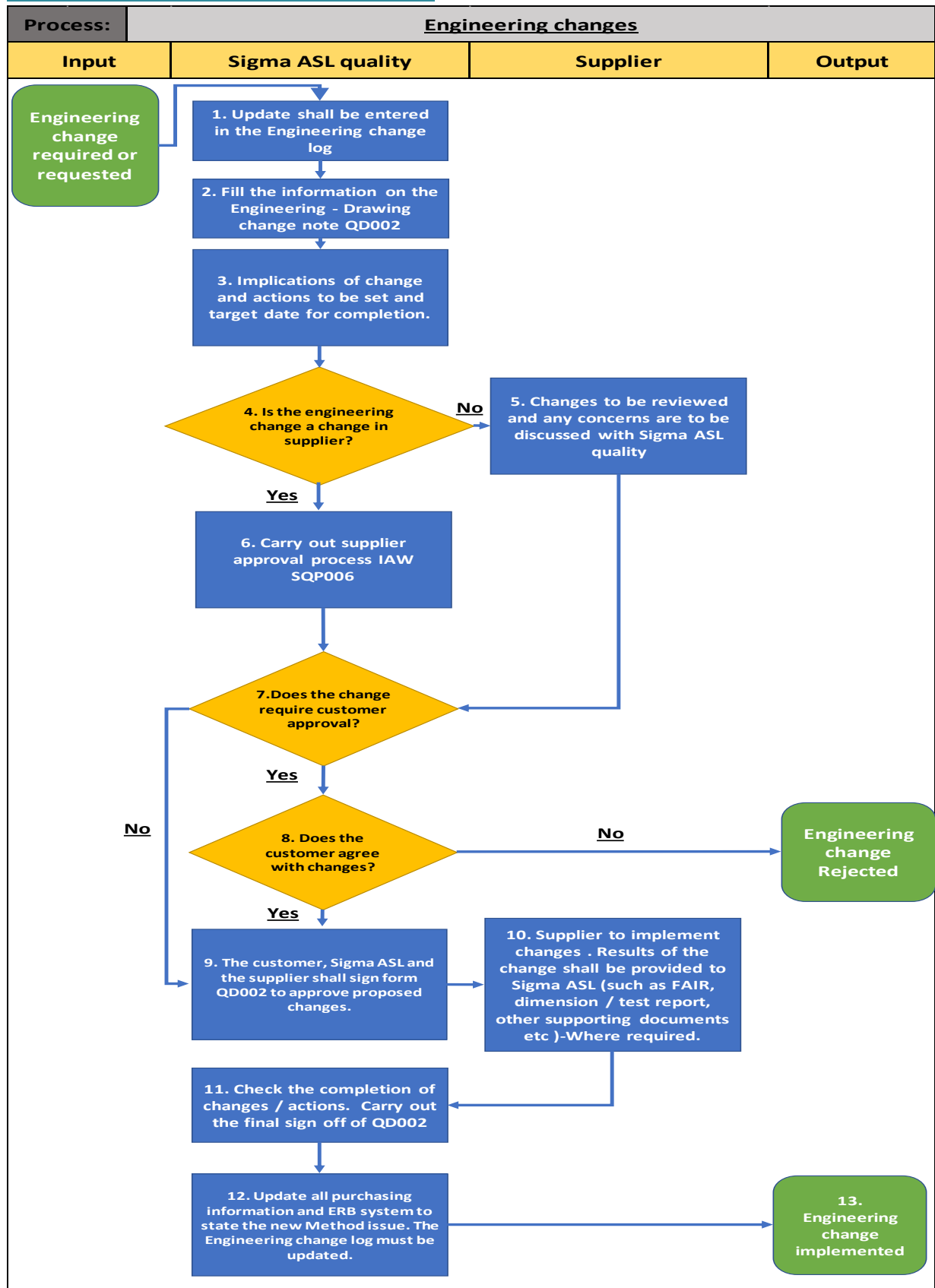
3.2.3 Post Change Checks

After the engineering change has been approved, as shown in the below swim lane results of the change shall (if required) be submitted to Sigma ASL whom will communicate these up to the customer. The results will state:

- Part conformity
- Any changes on capacity / Lead times
- Any potential further risks

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3.2.4 Swim lane for Engineering changes



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3.2.5 Swimlane Description

Start	Engineering change required or requested	Input
	<ul style="list-style-type: none"> - An engineering change has been requested by the customer or is required for production purposes. 	
1	Update shall be entered in the engineering change log	Action
	<ul style="list-style-type: none"> - Enter the necessary information in the Engineering change log. 	
2	Fill the information on the Engineering - Drawing change note QD002	Action
	<ul style="list-style-type: none"> - Fill out change note QD002 with all the necessary information. 	
3	Implications of change and actions to be set and target date for completion.	Action
	<ul style="list-style-type: none"> - Where actions have been set, the name of the person delegated shall be stated. - When actions have been complete the person who completed it will sign and date next to the action. 	
4	Is the engineering change a change in supplier?	Decision
	<ul style="list-style-type: none"> - Does this change mean a different supplier is required? For example if the casting method changes from sand to investment casting a different supplier will likely need to be used/found. 	
5	Changes to be reviewed and any concerns are to be discussed with Sigma ASL quality	Action
	Impact of proposed changes shall be considered such as, but not limited to; <ul style="list-style-type: none"> - Costing - Accreditation and relevant approvals for the product and premises - Resourcing - Lead time - Stock and WIP 	
6	Carry out supplier approval process IAW SQP006	Action
	<ul style="list-style-type: none"> - Supplier to be approved inline with SQP006. 	
7	Does the change require customer approval?	Decision
	<ul style="list-style-type: none"> - Check the customer specifications if the type of change requires approval. This can also be found in SQP-005 appendix A. 	
8	Does the customer agree with changes?	Decision
	<ul style="list-style-type: none"> - Discuss the change with the customer. 	
9	The customer, Sigma ASL and the supplier shall sign form QD002 to approve proposed changes.	Action
	<ul style="list-style-type: none"> - All parties to sign off the form. 	
10	Supplier to implement changes . Results of the change shall be provided to Sigma ASL (such as FAIR, dimension / test report, other supporting documents etc)-Where required.	Action
11	Check the completion of changes / actions. Carry out the final sign off of QD002	Action
	<ul style="list-style-type: none"> - If possible, attached any supporting evidence of change to the change note. - Ensure actions have been signed off in the 'Actions' section of the form. 	
12	Update all purchasing information and ERB system to state the new Method issue. The Engineering change log must be updated.	Action

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- Save the engineering change note onto the company server

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Engineering change implemented

Output

3.3 Specification reviews

The Sigma ASL Quality Department shall be responsible for the review of specifications and the final sign-off of specs prior to implementation.

Specification changes shall be carried out where required.

The relevant departments / people within Sigma ASL will be informed on changes affecting them itemised on QD001. Once they have reviewed and are acceptable for implementation, they shall sign and date next to their actions.

Risks identified shall be mitigated within form QD001 relevant to this process.

Once complete the specification update form shall be attached to the new issued spec and saved in the specification folder of the common drive.

Specification reviews shall be carried out by an authorised person as stated in the ASD

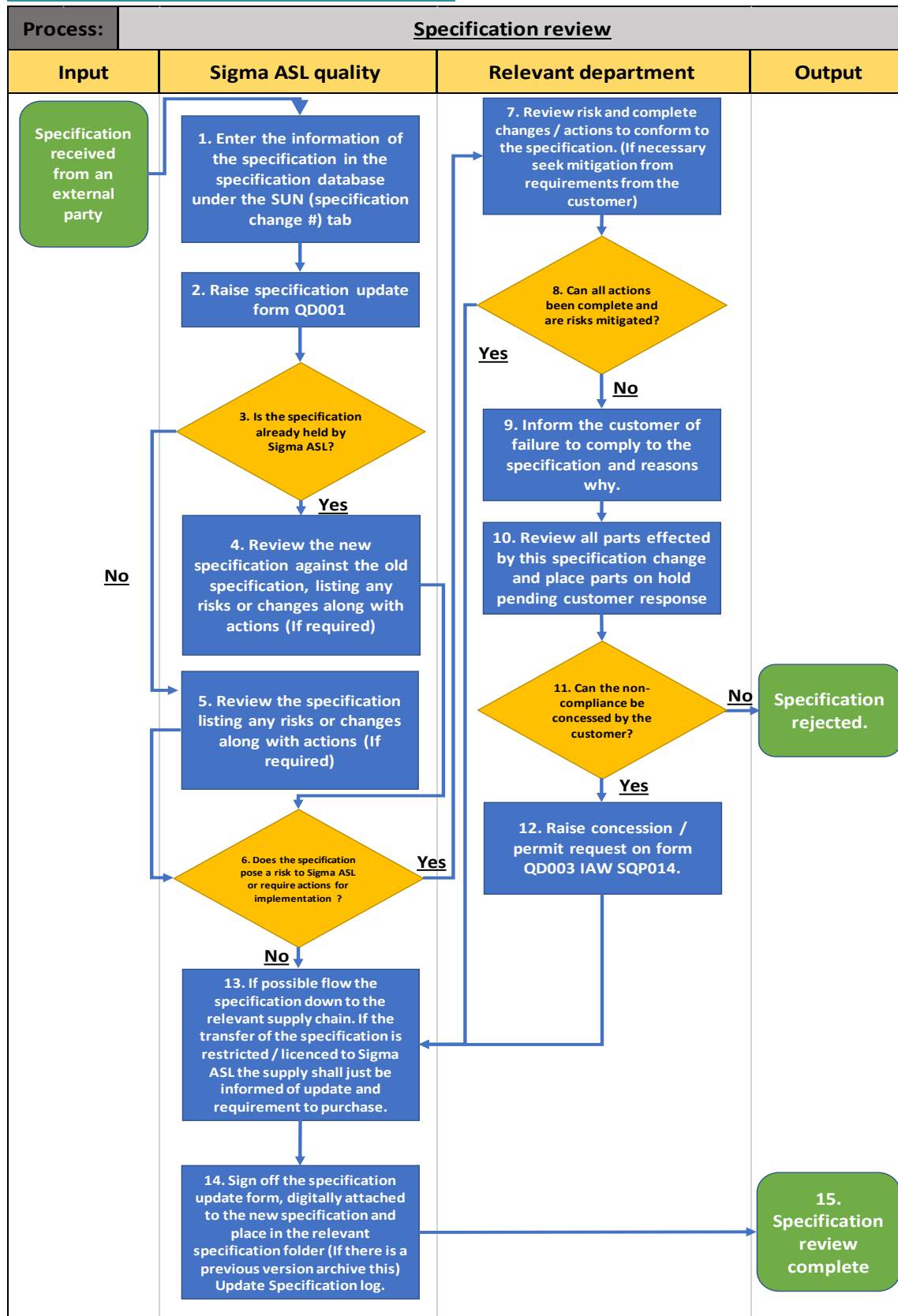
Sign off for risk analysis of specification reviews shall only be carried out by personnel approved in the ASD.

3.3.1 Resource

- Specification Log
- Specification update form QD001

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3.3.2 Swim lane for Specification reviews



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3.3.3 Swimlane Description

Start	Specification received from an external party	Input
	- Specification received/purchased	
1	Enter the information of the specification in the specification database under the SUN (specification change #) tab	Action
	- Enter relevant information into the Specification change tab of the specification log.	
2	Raise specification update form QD001	Action
	- Populate form QD001 with required information of the newly received specification.	
3	Is the specification already held by Sigma ASL?	Decision
	- Check the specification log to see if an older issue is held.	
4	Review the new specification against the old specification, listing any risks or changes along with actions (If required)	Action
	- Check the change log (If there is one) and review every paragraph for changes. - List the changes on form QD001.	
5	Review the specification listing any risks or changes along with actions (If required)	Action
	- Look through the changes and assess whether they have an impact on the business or product. - If there any list them out against the relevant department.	
6	Does the specification pose a risk to Sigma ASL or require actions for implementation?	Decision
	- If any risks have been identified assess if they have an impacts pose a risk.	
7	Review risk and complete changes / actions to conform to the specification. (If necessary, seek mitigation from requirements from the customer)	Action
	- Assess the risks and complete the necessary changes to allow confirmation to the specification. - When risks have been eliminated and actions complete the relevant personnel will sign that is has been complete (On form QD001).	
8	Can all actions been complete and are risks mitigated?	Decision
	- Decide if the identified risks can be actioned and mitigated.	
9	Inform the customer of failure to comply to the specification and reasons why.	Action
	- The risks cannot be mitigated and pose to much of an issue/threat to the company/supply chain. - Inform the customer that we cannot comply to this specification.	
10	Review all parts effected by this specification change and place parts on hold pending customer response	Action
	- Work out all parts and processes that are affected by this specification. - Place all affected parts on hold and inform any suppliers producing these parts to place the parts on hold.	
11	Can the non-compliance be conceded by the customer?	Decision
	- Find out from the customer is a concession is allowed to mitigate the non-compliance against this specification.	

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12	Raise concession / permit request on form QD003 IAW SQP014.	Action
	<ul style="list-style-type: none"> - Fill out concession/permit request form QD003. - Send populated concession to relevant person at the customer. 	
13	If possible, flow the specification down to the relevant supply chain. If the transfer of the specification is restricted / licenced to Sigma ASL the supply shall just be informed of update and requirement to purchase.	Action
	<ul style="list-style-type: none"> - If it is a customer specification forward this onto the relevant supplier. - If it is a purchased national/international specification inform the supplier of the update. This cannot be transferred and must be purchased by the supplier themselves due to licensing. 	
14	Sign off the specification update form, digitally attached to the new specification and place in the relevant specification folder (If there is a previous version archive this) Update Specification log.	Action
	<ul style="list-style-type: none"> - Relevant personnel to sign off the completed form. - Attach this to the now review specification and file this into the specification log. 	
15	Specification review complete	Output
	<ul style="list-style-type: none"> - Review process is complete. 	

3.4 Quality documentation changes

3.4.1 Quality procedures and work instructions

Changes made to Quality Procedures (QP) and Work Instructions (WI) shall only be carried out by the Sigma ASL Quality Department. This shall be reflected on the ASD.

1. To update QP and WI these shall have the necessary changes made by an Approved Person in the ASD.
2. These initial changes shall be done in a draft copy of the document.
3. The document will then be reviewed by another authorised person and the relevant section of the document will have the issue updated and signed by both the person who made the change and the person as reviewed and accepted it.
4. The previous copy shall be placed into archive and replaced with the new issue.
5. The issue change shall be recorded within the Specification database.
6. The Updated issue of the document will be communicated to the relevant departments and the supply chain (Where applicable). The distribution requirements (Internal, supply chain and website) are shown where applicable in the specification database.

There shall be no hard copies kept of quality procedures and work instructions. If these documents are printed, they shall be endorsed with un-controlled copy.

3.4.2 Quality Forms

Changes made to quality forms shall only be carried out by the Sigma ASL quality department. This shall be reflected on the ASD

1. Any person has permission to request changes to relevant Quality Forms.

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2. These initial changes shall be done in a draft copy of the document.
3. When complete, the change log for the individual form shall be updated (First tab of the excel document or as detailed on a word document)
4. The previous copy shall be placed into archive and replaced with the new issue.
5. The issue change shall be recorded within the Specification database.

3.4.3 Other quality documents relating to product

3.4.3.1 PFMEA

FMEA's created by Sigma ASL shall have the changes controlled by an issue tab at the start of the document. Any changes made shall be listed in this control log. After which the issue of the FMEA may be updated and flown down to all interested parties.

It shall be the responsibility of the engineering / quality department to carry out FMEA updates.

3.4.3.2 FAIR

Changes to FAIRs shall be carried out by the Engineering / Quality department. Where a FAIR is requiring a change be it from a change of supply or other circumstance the quality/engineering department shall make the necessary changes / updates and up issue the FAIR. The up issue shall be shown on the FAIR log and the old issue FAIR is to be archived.

4.0 - Communication of changes to customers

Changes by the organisation or its supply chain relating to a part / product and its processes may require communication to the customer. Every customer requirement differs, thus Sigma ASL quality must check prior to making a change what the customer requirements are for a new FAIR, specific documentation to submit etc. SQP-005 – Appendix A has been created to record this information. This document shall list the instances where changes require:

- A new FAIR / Delta
- Customer approval through customer specific documentation / systems.
- Proving / acceptance requirements.

Where a customer does not define these requirements in their specifications, Sigma ASL shall contact the customer to seek their requirements prior to making changes.

5.0 - Glossary

ASD – Approved Signatory Database

QP - Quality Procedure

WI – Works Instruction

PFMEA – Process Failure Mode and Effectiveness Analysis

FAIR – First Article Inspection Report

ECN – Engineering Change Note

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