ELIMINATION OF EXTERNAL AND INTERNAL AUDIT FINDINGS RELATED TO MISALIGNED DOCUMENTATION

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ABSTRACT

An audit is a process that requires careful preparation and a walkthrough of a potentially complex operational trail to validate system compliance and, conversely, uncover weaknesses if any. Among the recent findings in onsemi Carmona is "misaligned documentation" of different Quality System-related documents. This includes Process FMEA, Control Plan, Work Instruction, Preventive Maintenance (PM)/Calibration Procedure, and Total Control Methodology (TCM).

This paper discusses the strategy of addressing the issue of "misaligned documentation" exploring the comprehensive root cause analysis and validation process. The paper further discusses the customized system that was developed to detect and flag any incidence of documentation misalignment every time a process change is initiated by anyone. The system is called Document Alignment Matrix (DAM). In the pilot testing that was done, the system was proven to force the alignment of documentation in the Quality System.

1. 0 INTRODUCTION

In any industry, compliance to a related standard is a must and to ensure the company's compliance with these standards; an audit takes place. To keep the business going, audit plays a vital role in identifying risks, assessing compliance, and validating the effectiveness of the organization's defined controls and procedures. The Auditors rely on the documentation provided by the company on which they evaluate the processes, controls, and regulatory obedience. The challenge arises when the documented requirements across the Quality System related documents being examined during the audit do not align. This is known as Misaligned Documentation (MD), and it is commonly being raised as a nonconformance that needs to be addressed.

The internal audits (IA) and external audits (EA) revealed several incidents of misaligned documentation (MD) from January 2019 to July 2021. The IA recorded 17 findings, while the EA noted five findings related to MD. Figure 1 shows the total number of MD incidents per year, Figure 2 shows the distribution of MD incidents by Assembly process, and Figure 3 shows the trend of MD incidents at Wafer Saw process. Appendix A contains the breakdown of MD incidents by department.

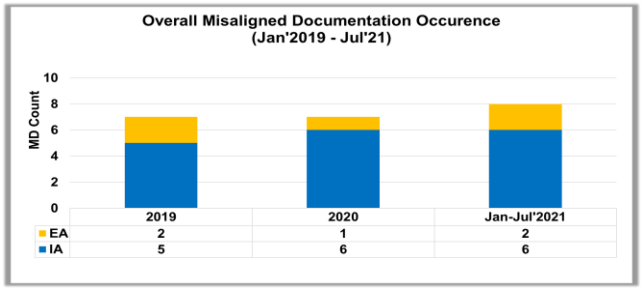

Figure 1. Trend Chart of Misaligned Documentation. The chart shows the occurrence of findings related to MD during external and internal audits.

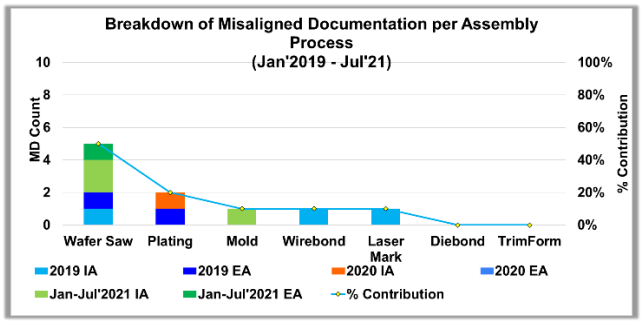

Figure 2. Distribution of Misaligned Documentation by Assembly Processes. The graph shows the number of findings in which the Wafer Saw process has the highest count of MD.

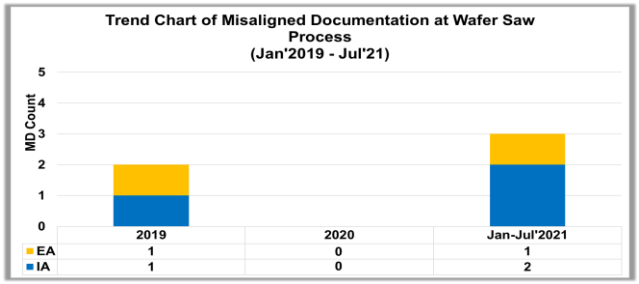

Figure 3. Trend Chart of Misaligned Documentation at Wafer Saw. The chart shows the incidences of MD at the Wafer Saw process from January 2019 to July 2021.

MD is one of the top DNV (Automotive Certifying Buddy) audit findings across all onsemi sites and this is critical as this matter may be escalated to a "Major Finding". Any repeat finding related to misaligned documentation may lead to the site or company's Automotive Certificate's cancellation. To avoid this from happening and to effectively address this repetitive issue, three sub-processes identified in Detailed Process Mapping (Appendix B) where the issue might have occurred were covered. These sub-process steps are: (1) Identify all affected documents to be revised, (2) Revise all affected documents based on the identified requirement to be documented and (3) Review the alignment of revised requirements to all the affected documents.

1.1 Identify all affected documents to be revised.

This step involves identifying all the types of documents that are impacted by the change or revision of a certain requirement. These documents may include PFMEA, Control Plan, Work Instruction, Process Specs, PM/CAL, and TCM. Document Owners are responsible for identifying all the affected documents and ensuring that they are consistent and aligned with the revised requirement. If Document Owners miss or overlook any document that is also affected by the change, this may result in misaligned documentation and therefore, it is important to identify all the affected documents accurately and comprehensively in this step.

1.2 Revise all affected documents based on the identified requirement to be documented.

This step involves revising all the types of documents that are impacted by the change or revision of a certain requirement. Document Owners are responsible for revising all the affected documents and ensuring that they are consistent and aligned with the revised requirement. If Document Owners fail to revise all the affected documents or do not coordinate with the related document owners during the documentation of a certain requirement, this may result in misaligned documentation, which can cause errors, inconsistencies, and inefficiencies in the process execution and quality assurance.

1.3 Review the alignment of revised requirements to all the affected documents.

In this process, the alignment check might not be performed by the change originator as this process takes much of their time checking all the other documents one by one. The alignment check involves checking the consistency and coherence of the revised requirement with all the types of documents that are impacted by the change or revision. The change originator is responsible for reviewing the alignment of revised requirements to all the affected documents and ensuring that there are no discrepancies or inconsistencies between them. If the change originator does not perform the alignment check or performs it inadequately, this may result in misaligned documentation.

2. 0 REVIEW OF RELATED WORK OR LITERATURE

Refer to 1.0 Introduction.

3.0 METHODOLOGY

The structured approach of the DMAIC problem solving was used to address the repetitive occurrence of external and internal audit findings related to misaligned documentation. This may possibly occur during the identification of affected documents to be revised, the revision of all affected documents based on the identified requirements to be documented, and the review of the alignment of revised requirements to all the affected documents.

3.1 Define

Considering the voice of the customer from both external and internal, an occurrence of MD has been identified that needs to be addressed and, with the gathered historical audit findings' data, this phase involves the identification of the focus process of this project. The team started with the process that has the greatest number of audit findings related to misaligned documentation.

3.2 Measure

This phase aims to review and validate the integrity of the number of misaligned documentation-related audit findings.

3.3 Analyze

Misaligned Documentation is a challenging issue that needs a systematic approach. For the team to recognize where this problem may occur, detailed process mapping and fishbone analysis have been used. The prioritization of all the identified potential root causes or Key Process Input Variables (KPIVs) was done using the Cause-and-Effect Matrix. The validation of the KPIVs was done by backtracking the revision history of (1) documents that were revised by the outgoing document owner and checking the succeeding revisions made by the new document owner if with misaligned documentation, (2) a document that was revised but another affected document that contains the same requirement was not considered, (3) process' related documents were revised by other user and not checked if with misaligned documentation and (4) document revisions made but alignment check to other affected document was not performed that leads to misaligned documentation.

3.4 Improve

For all the validated KPIVs, preventive, not human dependent, and preventive, human dependent corrective actions were formulated from which the best one was chosen. The selection of the best corrective action / preventive action (CAPA) was based on the level of control, ease of implementation, and cost. A potential problem analysis has been made to ensure that the best-selected CAPA will not create another problem and that the execution will be efficient.

The system has undergone rigorous development and simulation testing to ensure that all errors are eliminated, and the controls are functioning properly. Since the system is newly deployed to all end users, its effectiveness is being monitored and evaluated on an ongoing basis.

3.5 Control

The process improvement that has been implemented requires continuous maintenance of its benefits. Therefore, the corrective and preventive action (CAPA) that has been identified for this process improvement has been documented in the Document Data and Quality Records Control documentation. This documentation is a standard procedure for ensuring the quality and integrity of data and records in the organization. Since there was no failure mode and effects analysis (FMEA) affected by this process improvement, no changes were made to the FMEA documentation.

4.0 RESULTS AND DISCUSSION

4.1 Define

Considering the voice of the customer (VOC) from both internal and external aspects and based on the historical data, the Wafer Saw process (Assembly) was identified as the focused process in this phase, as it accounted for 23% of all the occurrences of MD related findings from January 2019 to July 2021.

A cross-functional DMAIC team was formalized to address this repetitive issue of Misaligned Documentation. With the help and support of the management team, this project aims to eliminate the occurrence of audit findings related to MD.

4.2 Measure

The documentation of process requirements has been reviewed and two metrics were identified, namely MD count in IA (Internal Audit) and MD count in EA (External Audit). Since Misaligned Documentation is a finding raised by Auditors, who are certified to Automotive Standard (IATF16949:2016), and before being declared officially, the findings are agreed upon by the Auditors and Auditees, thus, mis-declaration of the count of MD finding is not possible.

With the data integrity ruled out, the counts of MD for both internal and external audits are true and correct. Also, an MSA for this type of Key Process Output Variable (KPOV) is therefore not needed.

4.3 Analyze

With the team's effort in reviewing the detailed process map and exchanging ideas during the generation of cause-and-effect analysis (Fishbone Diagram), 22 Key Process Input Variables (KPIVs) were identified (refer to Appendix C).

The identified KPIVs were streamlined, and the total number was reduced to 9 KPIVs and they were clustered into 4 KPIVs (see Appendix D). All of these were subjected to a thorough validation.

4.3.1 KPIV 1.0: No proper endorsement of process spec's scope from previous process owner (resigned/transferred to another process)

To validate this potential cause, the revision history of the document/s revised by the outgoing document owner was backtracked and checked for any misaligned documentation in the succeeding revisions made by the new document owner. Figure 4 shows the evidence of KPIV 1.0 actual validation.

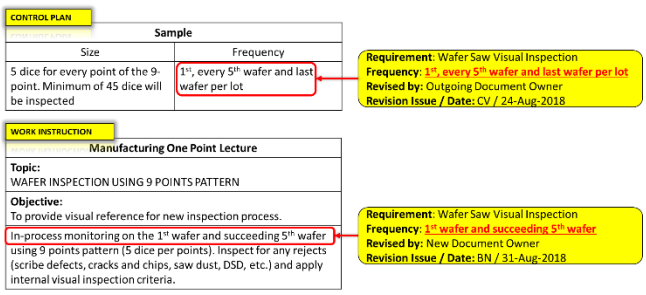

Figure 4. Control Plan revision (made by outgoing document owner) vs. reference work instruction revision (new document owner) related to inspection frequency was not aligned.

4.3.2 KPIV 2.0: Not all the related documentation was considered, some documents that were also affected by the changes to be made were missed, and not all the affected documents were revised.

This potential cause was validated through backtracking the revision history of a document which revealed that another document with the same requirement was overlooked, causing documentation misalignment.

Figure 5 shows the evidence of KPIV 2.0 validation, where the lock nut replacement frequency (yearly) in PM procedure did not match the Process FMEA's initial release.

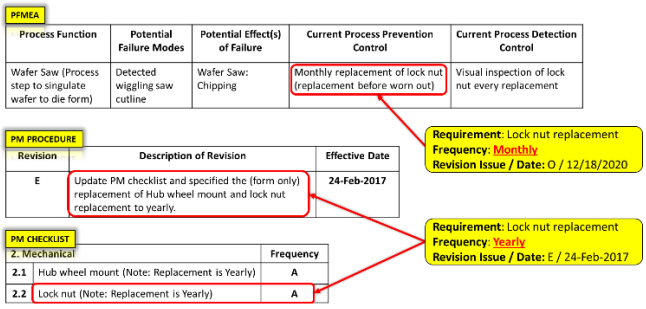

Figure 5. Lock nut replacement frequency (yearly) documented in PM procedure was not considered during Process FMEA's initial release.

4.3.3 KPIV 3.0: A document was revised by another document user, no coordination between the related documents' owners during the documentation of a certain requirement.

To validate this potential cause, the revision history of the process' related documents revised by another user was backtracked and checked for any misaligned documentation. Refer to Figure 6 for the evidence of KPIV 3.0 validation.

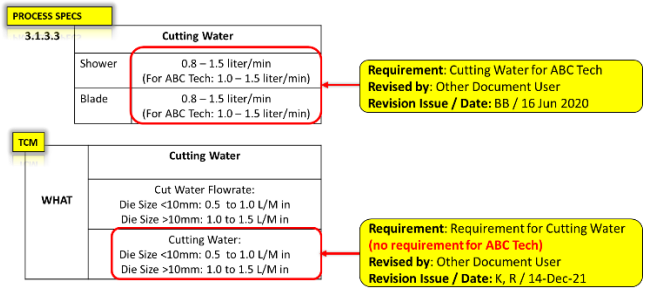

Figure 6. Cutting water requirement for ABC tech was documented by another document user as well as the requirement in the Positrol Plan (TCM) however, no specific requirement for ABC Tech was documented in TCM resulting in a misalignment of documents.

4.3.4 KPIV 4.0: The alignment review is not performed, not all revised documents were reviewed for required alignment.

This potential cause was validated through backtracking of document revisions made but an alignment check to other affected documents was not performed, leading to a misaligned documentation. The validation of the key process input variable (KPIV) 4.0 is shown in Figure 7.

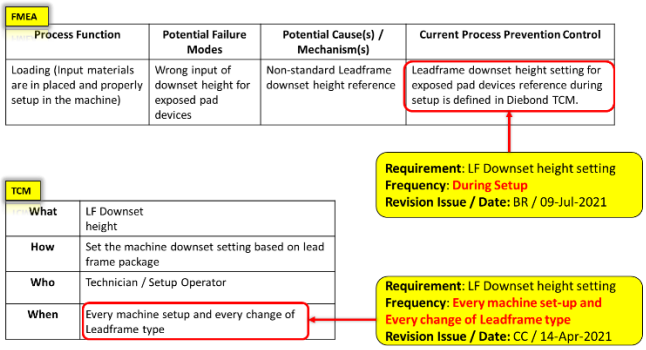

Figure 7. LF Downset height setting frequency (during set-up) vs. reference procedure (Every machine set-up and Every change of Leadframe type) were not checked for alignment upon revision.

4.4 Improve

A total of three CAPAs were formulated (as shown in Appendix F – Solution Selection Matrix), and the actions to be implemented focused on Poka-Yoke control (preventive, not human dependent) and were chosen for all the validated KPIVs.

An online system was developed that will ensure that in every change of requirements, all affected procedures are required to be updated and alignment of requirements is guaranteed. This online system is called the Document Alignment Matrix (DAM).

4.4.1 Document Alignment Matrix (DAM) System

The simulation test demonstrated the system's functionality, which involved two major processes: creating and approving change requests. These processes are depicted in Figure 8 and 9, which shows the flowcharts of each step.

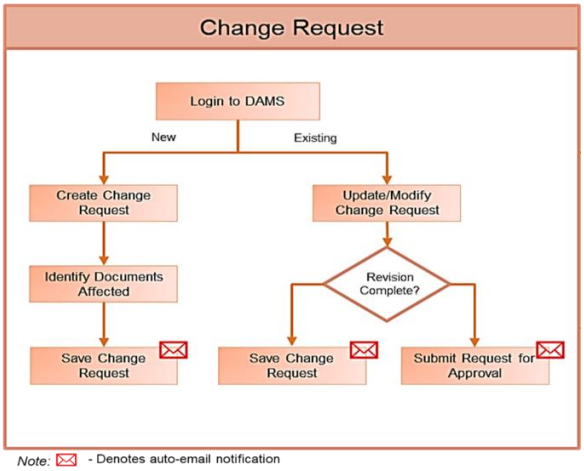

Figure 8. Change Request Flowchart. This shows the steps and decision points involved in creating a change request for the documentation of process requirements.

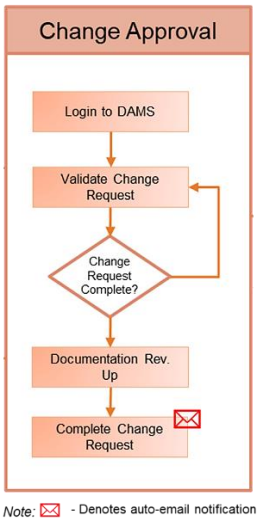

Figure 9. Change Approval Flowchart. This diagram shows the steps and decision points involved in reviewing and approving a change request for the documentation of process requirements.

The system offers the following features:

1. Repository of all documented requirements that reside in all document types.
2. List all related documentation that will be affected by the change.
3. Notifies document owners of every change request as well as the DCC and DAM Super User on the Cc List.
4. Integrates with the PFMEA SharePoint to capture updated items related to the document change request.

4.4.1.1 The repository of all documented requirements that reside in all document types:

The repository of all documented requirements that reside in all document types is a feature of the online system that enables the Document Owners to search for all the documents that contain a specific requirement that needs to be revised. The Document Owners can enter a unique term or keyword related to the requirement, and the online system will retrieve the requirement from its database or reference mapping matrix. The online system will then show all the documents that have the same requirement, along with their document number and document title. This feature can help to improve the efficiency and accuracy of identifying and revising all the affected documents based on the revised requirement.

4.4.1.2 Lists all the related documentation that will be affected by the change.

The online system will generate a summary of the documents that are impacted by the selected requirement change. The summary will include the document type, name, and location of each affected document. The Document Owner can use the summary to identify and revise the documents that need to be updated based on the revised requirement.

4.4.1.3 Notifies the document owners for every change request as well as the Document Control and DAM Super User on the Cc List

The online system will notify the owners of the documents that are impacted by the selected requirement change. The notification will inform them that they need to update their documents based on the revised requirement. The notification will also include the Routing System's traceable change ID number for each document. The change request will only proceed to the "For Approval" status after all the impacted documents are updated with the corresponding change ID number.

4.4.1.4 Integration with PFMEA SharePoint to capture updated items related to the document change request.

The online system connects to the Process FMEA ATO Sharepoint site, which helps the Document Owners to find the documents that are affected by the change based on the documentation hierarchy. Figure 10 shows the online system integration to PFMEA flow.

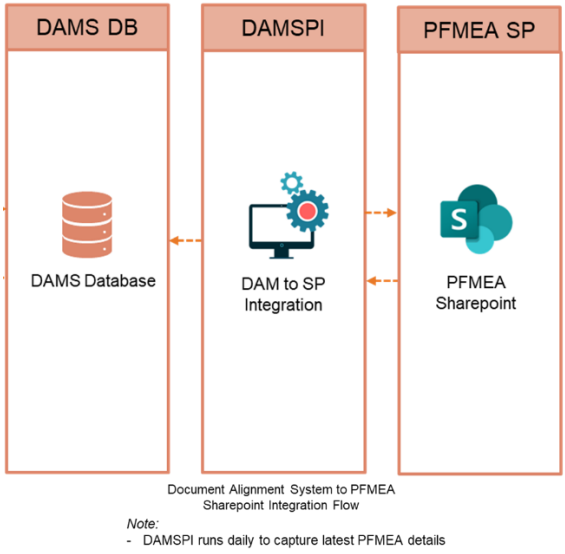

Figure 10. Document Alignment System (DAM) to Process FMEA Sharepoint Integration Flow.

This online system is a new product for the end users, so several tests of change requests were generated to mimic various situations that may arise when documenting the

process requirements. This way, it can ensure that the system meets the needs and expectations of the users and stakeholders.

Twenty (20) change request transactions were created with a total of 126 DAM ID combinations from PFMEA, Control Plan, Work Instruction, Process Specs, PM/CAL, and TCM documents.

All the change simulation tests generated were successfully transacted in the DAM System and alignment of requirements was ensured.

The revision of documents in the DAM System will also be updated once the provided change ID number by the respective change Requestor has been implemented in the Routing System. For the Revision of the Document process flow, refer to Appendix E.

Upon completion of a change request in the DAM System, several validation controls were put in place to ensure that all the affected documents are identified, revised, and documented requirements' alignment is guaranteed. Refer to Figure 11 for the trend chart of MD after simulation tests have been done in the DAM system.

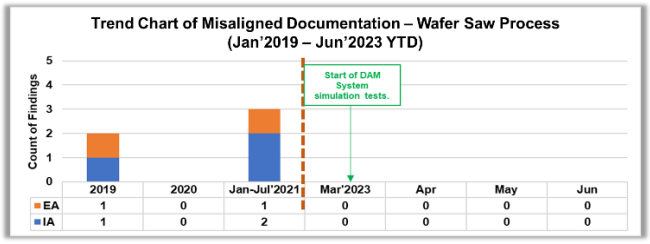

Figure 11. Trend Chart of Misaligned Documentation from Jan. 2019 – Jun. 2023 Year-to-Date (Wafer Saw Process). ZERO MD occurrence from Mar'2023 when DAM System simulation tests started.

5.0 CONCLUSION

The foregoing discussion demonstrated the effectiveness of a net-based system called DAM in ensuring proper alignment of Quality Systems documentation every time a change is initiated by anyone. This benefited the alignment of Process FMEA, Control Plan, Work Instruction, Preventive Maintenance (PM)/Calibration Procedure, and Total Control Methodology (TCM).

Like any problem-solving endeavor, crucial to the development of effective solutions is the thoroughness in the analysis of the problem.

6.0 RECOMMENDATIONS

Considerations should also be taken for the other processes regarding their inclusion in the DAM System's database. The alignment of procedures must be ensured for all the Quality System-related documents across all the manufacturing processes, in order to fully eliminate the possibility of audit findings related to misaligned documentation.

The DAM System's linkage to CAMSTAR must also be explored to further optimize the benefit of alignment and system automation.

7.0 ACKNOWLEDGMENT

The Authors would like to thank the onsemi Carmona management for the confidence and support provided to make this project successful:

Ronnie Manubay, Quality Assurance Manager, for providing the needed support to achieve successful implementation of this project.

Jill Mallorca, IS System Manager, for being instrumental in getting sources from the IT team to develop the DAM System.

Our sincere appreciation goes also to Josie Birog, Wilma De Guzman, and Ma Lee Diesta for the technical support; Dennis Remolacio and Peter Awayan, for their continuous support and guidance throughout the completion of the project.

8.0 REFERENCES

None

9.0 ABOUT THE AUTHORS

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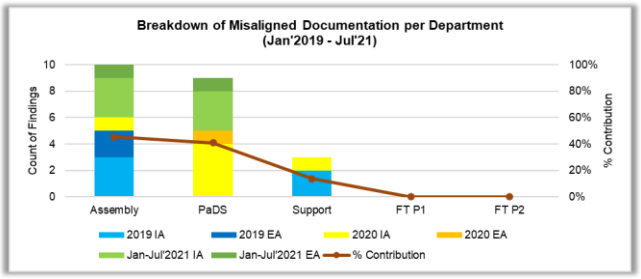
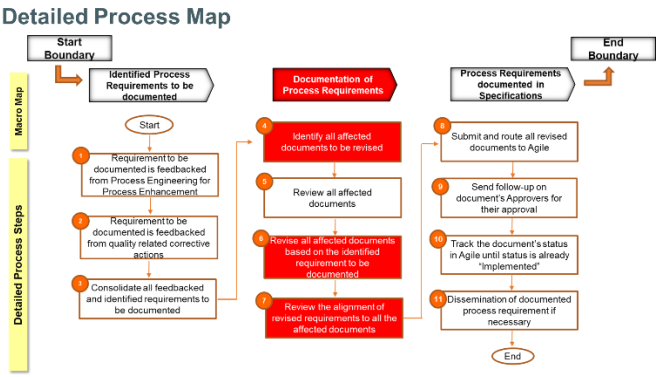
10.0 APPENDIX

Appendix A: Breakdown of Misaligned Documentation per Department



Appendix B: Detailed Process Mapping



Appendix C: 22 KPIVs Identified

C&E Matrix (22 KPIVs Identified) - Scoring and Selection

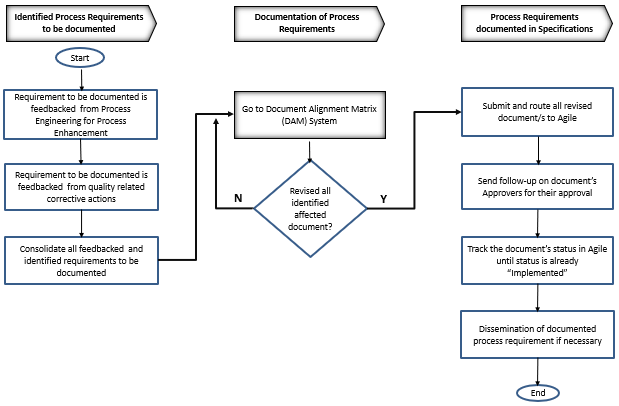
N	n	Process Step	Input	KPIV	Characteristic of Input (KPIV)	Specification / Criteria	Occurence of Misaligned Documentation	Occurrence of Process Nonconformity	Occurrence of Customer Complaint / CAR	Total	Rank	Selected / Discarded?
					Process Output / Importance to Customer		9	6	6			
1	1.1	Man	Fishbone	1	No proper endorsement of process spec's scope from previous process owner (resigned)	Process spec's scope is properly endorsed by outgoing process owner to incoming process owner	9	6	6	153	1	Selected
1	1.2	Man	Fishbone	2	No proper endorsement of process spec's scope from previous process owner (transferred to other process)	Process spec's scope is properly endorsed by outgoing process owner to incoming process owner	9	6	6	153	1	Selected
1	1.3	Man	Fishbone	3	Document owners belong to multiple groups (equipment / process, mfg., etc.)	Only 1 document owner is acceptable in Agile. 68AON3165HE - Agile PLM User Guide	1	1	1	21	12	Discarded
1	1.4	Man	Fishbone	4	No verifier from Quality during revision of documents	12MPO40501A - Document, Data and Quality Records Control Appendix A, Internal Approval Matrix QA Manager is part of the approval	1	1	1	21	12	Discarded
1	1.5	Man	Fishbone	5	Not aware on the procedure for documentation of requirement	12MPO40501A - Document, Data and Quality Records Control 3.1.2 Specs Revision 3.1.2.1 Originator identifies the need to revise, or obsolete a procedure for a given process, and download editable copy from AGILE /DocServer, please refer to this link for the procedure in specs revision. 3.1.2.2 Originator to reflect revision in the downloaded copy and changes should be in red font or by using track changes for ease traceability.	1	1	1	21	12	Discarded
1	1.6	Machine	Fishbone	6	Procedure for documentation of requirement is not clearly defined	12MPO40501A - Document, Data and Quality Records Control 3.1.2 Specs Revision 3.1.2.1 Originator identifies the need to revise, or obsolete a procedure for a given process, and download editable copy from AGILE /DocServer, please refer to this link for the procedure in specs revision. 3.1.2.2 Originator to reflect revision in the downloaded copy and changes should be in red font or by using track changes for ease traceability.	1	1	1	21	12	Discarded
1	2.1	Material	Fishbone	7	Multiple Document Owners for the related specifications of a process	Only 1 document owner is acceptable in Agile. 68AON3165HE - Agile PLM User Guide	1	1	1	21	12	Discarded
1	2.2	Material	Fishbone	8	Not all related documentations were considered	All documents affected by the change should be considered, reviewed and revised. 12MPO40501A - Document, Data and Quality Records Control	9	6	6	153	1	Selected
4	4.3	Material	Fishbone	9	Document was revised by another document user	Documentation of certain requirement is being coordinated with affected document owners and obtain approval. 12MPO40501A - Document, Data and Quality Records Control	6	3	3	90	8	Selected
4	4.4	Identify all affected documents to be revised	Process Engineer, Equipment Engineer and Manufacturing Trainer	10	Missed to consider certain document that is also affected by the changes to be made	All documents affected by the change should be considered, reviewed and revised. 12MPO40501A - Document, Data and Quality Records Control	9	6	6	153	1	Selected
4	4.5	Identify all affected documents to be revised	Docs to be reviewed (FMEA and other QS Docs)	11	---	---	1	1	1	21	12	Discarded
4	4.6	Identify all affected documents to be revised	12MPO40501A - Document Data and Quality Records Control	12	---	---	1	1	1	21	12	Discarded
5	5.1	Revise all affected documents based on the identified requirement to be documented	Process Engineer, Equipment Engineer and Manufacturing Trainer	13	Not all affected documents were revised	All documents affected by the change should be considered, reviewed and revised. 12MPO40501A - Document, Data and Quality Records Control	9	6	6	153	1	Selected
5	5.2	Revise all affected documents based on the identified requirement to be documented	Process Engineer, Equipment Engineer and Manufacturing Trainer	14	Requirement was wrongly documented	All documents affected by the change should be considered, reviewed and revised. 12MPO40501A - Document, Data and Quality Records Control	3	1	1	39	10	Discarded
5	5.3	Revise all affected documents based on the identified requirement to be documented	Process Engineer, Equipment Engineer and Manufacturing Trainer	15	Un-aware that requirement to be documented is linked to a certain specification	Process spec's scope is properly endorsed by outgoing process owner to incoming process owner	3	1	1	39	10	Discarded
4	4.7	Revise all affected documents based on the identified requirement to be documented	Process Engineer, Equipment Engineer and Manufacturing Trainer	16	No coordination between related documents' owners during documentation of certain requirement.	Documentation of certain requirement is being coordinated with affected document owners and obtain approval. 12MPO40501A - Document, Data and Quality Records Control	6	3	3	90	8	Selected
5	5.2	Revise all affected documents based on the identified requirement to be documented	Docs reviewed (FMEA and other QS Docs)	17	---	---	1	1	1	21	12	Discarded
5	5.3	Revise all affected documents based on the identified requirement to be documented	12MPO40501A - Document Data and Quality Records Control	18	---	---	1	1	1	21	12	Discarded
6	6.1	Review the alignment of revised requirements to all the affected documents	Process Engineer, Equipment Engineer and Manufacturing Trainer	19	Alignment review is not performed	Alignment of documented requirement on different specifications must be checked by Document Originator for every revisions they submit. 12MPO40501A - Document, Data and Quality Records Control	9	6	6	153	1	Selected
6	6.1.1	Review the alignment of revised requirements to all the affected documents	Process Engineer, Equipment Engineer and Manufacturing Trainer	20	Not all revised documents were reviewed for requirement alignment.	Alignment of documented requirement on different specifications must be checked by Document Originator for every revisions they submit. 12MPO40501A - Document, Data and Quality Records Control	9	6	6	153	1	Selected
6	6.2	Review the alignment of revised requirements to all the affected documents	Revised Docs (FMEA and other QS Docs)	21	---	---	1	1	1	21	12	Discarded
6	6.3	Review the alignment of revised requirements to all the affected documents	12MPO40501A - Document Data and Quality Records Control	22	---	---	1	1	1	21	12	Discarded

Appendix D: 4 KPIVs Identified after grouping.

C&E Matrix (4 KPIVs Identified after grouping)

N	n	Process Step	Input	Rank	KPIV # Assigned	Characteristic of Input (KPIV)	Specification / Criteria	Occurence of Misaligned Documentation	Occurrence of Process Nonconformity	Occurrence of Customer Complaint / CAR	Total	Rank	Selected / Discarded?
						Process Output / Importance to Customer		9	6	6			
1	1.1	Man	Fishbone	1	1	No proper endorsement of process spec's scope from previous process owner (resigned)	Process spec's scope is properly endorsed by outgoing process owner to incoming process owner	9	6	6	153	1	Selected
1	1.2	Man	Fishbone	1		No proper endorsement of process spec's scope from previous process owner (transferred to other process)	Process spec's scope is properly endorsed by outgoing process owner to incoming process owner	9	6	6	153	1	Selected
2	2.2	Material	Fishbone	2	2	Not all related documentations were considered	All documents affected by the change should be considered, reviewed and revised. 12MPO40501A - Document, Data and Quality Records Control	9	6	6	153	1	Selected
4	4.4	Identify all affected documents to be revised	Process Engineer, Equipment Engineer and Manufacturing Trainer	2		Missed to consider certain document that is also affected by the changes to be made	All documents affected by the change should be considered, reviewed and revised. 12MPO40501A - Document, Data and Quality Records Control	9	6	6	153	1	Selected
5	5.1	Revise all affected documents based on the identified requirement to be documented	Process Engineer, Equipment Engineer and Manufacturing Trainer	2		Not all affected documents were revised	All documents affected by the change should be considered, reviewed and revised. 12MPO40501A - Document, Data and Quality Records Control	9	6	6	153	1	Selected
4	4.3	Material	Fishbone	3	3	Document was revised by another document user	Documentation of certain requirement is being coordinated with affected document owners and obtain approval. 12MPO40501A - Document, Data and Quality Records Control	6	3	3	90	8	Selected
5	5.3	Revise all affected documents based on the identified requirement to be documented	Process Engineer, Equipment Engineer and Manufacturing Trainer	3		No coordination between related documents' owners during documentation of certain requirement.	Documentation of certain requirement is being coordinated with affected document owners and obtain approval. 12MPO40501A - Document, Data and Quality Records Control	6	3	3	90	8	Selected
6	6.1	Review the alignment of revised requirements to all the affected documents	Process Engineer, Equipment Engineer and Manufacturing Trainer	4	4	Alignment review is not performed	Alignment of documented requirement on different specifications must be checked by Document Originator for every revisions they submit. 12MPO40501A - Document, Data and Quality Records Control	9	6	6	153	1	Selected
6	6.1.1	Review the alignment of revised requirements to all the affected documents	Process Engineer, Equipment Engineer and Manufacturing Trainer	4		Not all revised documents were reviewed for requirement alignment.	Alignment of documented requirement on different specifications must be checked by Document Originator for every revisions they submit. 12MPO40501A - Document, Data and Quality Records Control	9	6	6	153	1	Selected

Appendix E: Requirement Documentation Process Flow



Appendix F: Solution Selection Matrix

KPIV No.	KPIV Group No.	Validated KPIVs/Cause	CAPA No.	CAPA Options	Ease of Implementation	Cost involve in Implementation	Effectiveness	Risk to create other	<<< Selection Criteria	Decision (GO ≥ 90)	CAPA Category	Remark
					5	5	5	5	<<< Importance			
					<<Correlation of Solution to Criteria>>				Total			
1, 2	1	No proper endorsement of process spec's scope from previous process owner (transferred to other process, resigned)	1	Process orientation / training	5	5	1	1	60	NO GO	Preventive Human Dependent	
			2	Develop an online system that ensures that in every change of requirements, all affected procedures are required to be updated and alignment of requirements are guaranteed.	5	5	5	5	100	GO	Preventive Not Human Dependent	
8, 10, 13	2	Not all related documentations were considered, reviewed and revised	-	Same as CAPA #2	---	---	3	---	---	---		
			3	Use Document Linkage Checklist every revision made on FMEA, CP, WI, TCM, PM/CAL Specs, SOP, etc.	5	5	3	3	80	NO GO	Preventive Human Dependent	This is an existing control but will have to be stopped because it can be taken cared of by CAPA#2 already.
9, 16	3	Document was revised by other document user without proper coordination with Document Owner	-	Same as CAPA #2	---	---	---	---	---	---		
			-	Same as CAPA#3	---	---	---	---	---	---		
19, 20	4	Alignment check was not performed after revision is made to all affected documents	-	Same as CAPA #2	---	---	---	---	---	---		
			-	Same as CAPA#3	---	---	---	---	---	---		