Quality Manual

ISO 9001:2008

ISO 9001:2015

SAE CIRCUITS, INC.

4820 63rd Street

Suite 100

Boulder, CO 80301

USA

www.saecircuits.com

Table of Contents

1. Company Information

SAE Circuits is located in Boulder, Colorado. We have been a technology and service leader in printed circuit manufacturing since 1972. We strive to provide our customers with the highest possible level of service with exception quality and delivery, which has enabled us to build on a solid foundation of past experience. We attribute our success to our relentless pursuit of customer satisfaction and our commitment to our employees, our community and the environment. Our philosophy remains "Build a high quality product, deliver on-time, and at a competitive price".

2. QMS Scope and Exclusions

2.1. Scope

The Quality Management System (QMS) for SAE Circuits applies to the operations conducted at 4820 63rd Street, Suite 100, Boulder, Colorado, 80301. The QMS has been designed to comply with the requirements *of ISO 9001:2008 and* ISO 9001:2015 and to ensure consistent quality of our products and services. The scope of our QMS is defined as follows:

The Manufacturing of Printed Circuit Boards,

with the focus on providing product to the customer

that meets or exceeds their expectations and specification.

We conform to the requirements of IPC-A-600 (current revision) - Acceptability of Printed Boards.
As part of our management system processes, SAE does not currently;

- Perform design services (all designs are supplied by our customers),
- Provide or conduct post-delivery activities,

Therefore, these items are not part of our Management Systems Scope.

2.2. *Excluded Standards and* Non-applicable Requirements

SAE Circuits does not design products; therefore, the requirements of *ISO 9001:2008, Section 7.3 "Design ad Development" and* ISO 9001:2015 Section 8.3 "Design and Development" is*/are* not applicable.

Another excluded standard is ISO 9001:2008 Section 7.5.1.f , which states "The organization shall plan and carry out production and service provision under controlled conditions. Controlled conductions shall include, as applicable f) the implementation of product release, delivery and post-delivery activities – post-delivery activities only."

3. Leadership and Management Responsibility

3.1. Commitment

3.1.1. Management actively demonstrates its leadership and commitment with respect to the QMS by: taking accountability for the effectiveness of the QMS, ensuring the quality policy and quality objectives are established and are compatible with SAE's context and strategic direction, ensuring the QMS requirements are integrated into SAEs' business processes, promoting the use of the process approach and risk-based thinking, ensuring resources needed are available. communicating the importance of effective quality management and of conforming to QMS requirements, ensuring the QMS achieves its intended results, engaging, directing and supporting personnel to contribute to the effectiveness of the QMS, promoting improvement, supporting other management roles to demonstrate their leadership as it

applies to their area of responsibility, and by participating in QMS planning, internal audits and management reviews.

3.1.2. Management's leadership is committed to maintaining and improving the QMS in order to continually satisfy customers by providing them with products and services that meets their specifications. Management ensures that customer requirements are met with the intention of enhancing customer satisfaction. This commitment is demonstrated by the development and implementation of the QMS, by formulating the quality policy, and by establishing measurable objectives against which QMS performance is evaluated and acted upon, in an effort to improve processing and the resulting products. Management ensures that employees understand the importance of meeting requirements, particularly those of our customers.

3.1.3. Management also demonstrates a commitment to quality by conducting periodic management reviews of the QMS and its processes. Based on factual information regarding performance and other feedback from customers, and in consideration of future customer needs, Management allocates resources as necessary to ensure conformity of product, and to improve the QMS, its processes, and resulting products and services, in order to promote customer satisfaction.

3.2. Quality Policy

3.2.1. Management's commitment to meeting requirements, satisfying customers, and improving the QMS, its processes and resulting products is reflected in the following quality policy:

The Management and Employees of SAE Circuits Colorado, Inc., proudly pronounce our commitment to Customer Satisfaction, through Continuous Improvement and by our dedication to providing defect-free products and services in a competitive environment.

3.2.2. Management reviews the above policy periodically during management review to ensure its continuing suitability, and that it remains appropriate for the company, that it includes a commitment to comply with requirements and to continually improve the QMS, and that it provides a foundation for measurable objectives against which performance can be evaluated. Management also ensures that all employees understand the policy, how it applies in their work, and how their performance relates to the achievement of quality policy objectives. The quality policy is also available to relevant interested parties, as appropriate.

3.3. Quality Objectives

3.3.1. Management has established measurable objectives for QMS performance that are derived from the Quality Policy. Such objectives serve as a foundation for reviewing performance at both the process and system level. The quality objectives take into account applicable requirements, are relevant to conformity of products and services and enhancement of customer satisfaction. Customer focus ensures quality objectives include measures for on-time delivery and at least one measurement of product conformity and customer satisfaction.

3.3.2. The Metrics worksheet in the QMS Planning Tool is used to identify and plan quality objectives and process measurements. Key objectives and measurements are monitored on an on-going basis and are addressed during Management Review meetings, along with an indication of a timeframe for their achievement and are used to implement the Quality Policy.

3.3.3. Along with planning the quality objectives, management has determined they are appropriate for SAE. Management plans methods and activities to achieve them. Such planning includes what will be done, what resources will be required, who will be responsible, when it will be completed and how the results will be evaluated.

3.3.4. The quality objectives are communicated through posting in the facility and/or reviewed during meetings. As necessary, quality objectives and the goals to achieve them are updated as appropriate.

4. QMS Overview

4.1. SAE's QMS, like the documentation describing it, is structured around the processes affecting the quality of products and services offered. The QMS has been developed and implemented to promote quality and improvement and is managed to meet the requirements of ISO 9001, and to meet all applicable regulatory and statutory requirements.

The QMS can be viewed as a system of processes that fall into two general categories: primary processes and support processes.

The *primary processes* involve product realization activities directly affecting quality of product intended for customers and these include (in general sequence):

Sales -> Purchasing -> Receiving -> Production -> Shipping

Or for products in existing inventory:

Sales -> Shipping

Support processes are those necessary for the successful operation and control of the primary processes and the QMS as a whole. These operate in parallel with primary process, and thus are not sequential: Calibration, Nonconformity, Corrective Action and Improvement, Documented Information, Internal Audit, Training and Competence, and Leadership and Management. Overviews of all QMS processes appear in Section 5 of this manual.

Outsourced processing is controlled in accordance with the Purchasing procedure, the results of which are verified according to the Receiving and Shipping procedure. Outsourced calibration service is controlled in accordance with the Calibration and Purchasing procedures, the results of which are verified according to the Calibration procedure. Outsourced internal audits (when used) are controlled in accordance with the Internal Audits and Purchasing procedures and the results are verified in accordance with the Internal Audits procedure.

A documented procedure has been established, implemented and maintained for each QMS process, regardless of whether it is a primary or a support process. Each procedure identifies the inputs to and outputs of the process and describes how those inputs are transformed into their respective outputs under controlled conditions. Each procedure also identifies responsibilities and authorities of personnel performing tasks in the process.

4.2. Responsibilities and Authorities

4.2.1. Management ensures that responsibilities and authorities are defined and communicated to all employees. Management is ultimately responsible for the quality of SAE's products, services and processes.

4.2.2. Due to the simplicity and size of SAE, organizational responsibilities and authorities for QMS activities are defined in operating procedures (see 4.1) and in Job Descriptions (see the Training and Competence procedure).

4.2.3. The Director, QA is currently the Quality Representative. As such, he is responsible for establishing, implementing and maintaining the QMS and ensuring it conforms to the requirements of ISO 9001. He is also responsible for reporting/reviewing performance information and improvement opportunities during Management Review, and for promoting awareness of customer requirements throughout the company and ensuring the integrity of the QMS will be maintained when changes to the QMS are planned and implemented. The Management Representative is responsible for and has authority for oversight of these requirements. He ensures there is organizational freedom and unrestricted access to all management to resolve quality management issues.

4.2.4. Though responsibilities and authorities ultimately reside with Management, they are delegated to competent personnel as necessary. All personnel who perform, manage, and/or verify work are responsible for the quality of products produced and services provided by SAE. All employees are responsible for complying with documented procedures and the direction of Management. All employees are authorized to identify and record problems relating to products, processes, and the quality management system as a whole, and to provide suggestions for improvement or recommendations for solving problems by initiating actions according to the Nonconformity, Corrective Action and Improvement procedure. All employees are also responsible for cooperating fully with internal audits.

4.2.5. Personnel are responsible for ensuring control over their activities and to complete work in a responsible and safe manner. All employees are responsible for maintaining the premises in a state of order, cleanliness, and repair consistent with processing needs. They are also responsible for identifying nonconforming product or service, stopping work as necessary, and controlling further processing until Management has been promptly notified and the problem has been corrected.

4.3. Quality Planning

4.3.1. Management ensures that QMS planning occurs in a proactive manner, and is carried out in order to meet the requirements of our customers and other relevant interested parties as well as our own internal requirements. QMS planning occurs at two levels: the process level and the system level.

4.3.2. Planning at the system level involves establishing the QMS processes and infrastructure necessary to meet the general requirements of customers and other interested parties, focusing on the ability of the system to effectively and efficiently meet all requirements. This planning is conducted with a multidisciplinary approach, and takes into consideration facility and equipment plans, handling, and value-added use of floor space as well as outsourced process considerations. This planning results in system-level processes and procedures that represent the planned arrangements described by QMS documentation.

4.3.3. The QMS Planning Tool ensures that Management identifies important considerations of the organization that are necessary to optimize the QMS' performance and thereby enhancing customer satisfaction. The QMS Planning Tool addresses the following:

a) The purpose of SAE.

b) SAE's strategic direction.

c) Relevant external and internal issues impacting the performance of the QMS and SAE's products and services.

d) Recognition of interested parties and their requirements that have an effect or have the potential to affect SAE's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements.

e) The boundaries and scope of the QMS.

f) Opportunities to enhance desirable effects and contribute to achieving improvement,

g) The organizational knowledge necessary to ensure conformity to requirements and for the operation of SAE's processes, and the means to maintain and upgrade organizational knowledge.

h) A communications plan that includes internal and external communications that are relevant to the QMS.

i) Reviewing the manufacturing operations to determine necessary process validations.

4.3.4. Risked-based thinking is applied to the QMS through the consideration of the internal and external issues and the requirements of relevant interested parties. The Risk Management Report identifies specific risks that need to be addressed to give assurance that the QMS can achieve its intended results, to prevent or reduce undesired effects, and achieve improvement. See the Leadership and Management procedure, and primary process procedures for on-going risk management. Risk-based thinking is also applied at the operational level for the product and service provision processes. The Risk Management Report also addresses operational-level risks.

4.3.5. The above system level planning has already been implemented and the resulting arrangements are currently adequate to meet the requirements of our customers. In general, the quality plan for providing products and services is to process them in a manner consistent with the existing planned arrangements described by QMS procedures. Where new manufacturing methods that involve significantly new or modified requirements are to be pursued, Management will ensure that quality planning is conducted, and that such planning is implemented and appropriately documented before promising to accept orders. See the Leadership and Management procedure and Production procedure.

4.3.6. Where changes to the QMS are planned, due to changes in technology or in the market, changes caused by relevant interested parties, changes to processes, procedures, or product and service requirements, introduction of new processes or products or services, etc., Management will ensure that the integrity of the QMS is maintained to ensure conformity of product and service to requirements. The full impact of such changes will be determined, as appropriate. Any such changes will be verified and validated to ensure conformity to internal and customer requirements and other relevant interested parties before implementation. Such QMS planning and change management is conducted during management review, or more frequently as circumstances dictate. See the Leadership and Management procedure.

4.3.7. Planning at the process level focuses on providing products and services to ensure conformity of the products and service to applicable requirements according to customer specifications and acceptance criteria, statutory and regulatory requirements, and any additional customer requirements. This planning also includes determining the processes and controls needed to manage critical items identified by customers, including production process controls when key characteristics have been identified, engaging management from multiple functions for operational planning and control, determining the process and services to be obtained from external providers, and establishing the controls necessary to prevent

the delivery of nonconforming products to customers. This planning is to establish processes and documentation specific to the products, services, and/or processes, and to identify specific resource requirements. This level of planning results in test procedures and/or inspection documents which identify required verifications to ensure conformity of the product, records demonstrating conformity, and methods for reacting when planned arrangements are not achieved.

4.3.8. As appropriate to SAE, customer requirements and the components manufactured to customers' specifications, SAE plans and manages product and service provision in a structured and controlled manner, including scheduled events performed in a planned sequence to meet requirements at acceptable risk and within resource and schedule constraints. This is accomplished through following our processes, and through constant cross-functional communications.

4.3.9. SAE has established, implemented, and maintained a process to plan and control manufacturing operations that are outsourced to approved external providers. This temporary transfer of work is managed through Purchase Orders, Travelers, and verification and inspections at Receiving and the accountability of all parts. See the Purchasing, Production, and Receiving and Shipping procedures.

4.4. Resource Management

4.4.1. Management ensures that resource requirements are determined and met where they are needed to effectively operate and control QMS processes, to maintain and improve the QMS, and to achieve customer satisfaction by meeting their requirements.

4.4.2. Resource requirements include human resources (including personnel and training resources), infrastructure resources (including buildings, workspace, process equipment, operating supplies, measuring equipment, documentation, and supporting services and utilities), and work environment resources (including safety, ergonomic and human/physical aspects of work being performed). Management ensures the environment necessary for the operation of processes and to achieve conformity of products and services is determined, provided, and maintained.

4.4.3. Resource needs may be identified within any QMS process, or they may arise in connection with management reviews, corrective actions, risk mitigations, internal audits, employee observations, etc. Resource needs are fulfilled according to the Purchasing procedure and competent personnel are on-boarded per the Training and Competence procedure.

4.5. Monitoring, Measurement, and Analysis

4.5.1. Monitoring and measurement methods to evaluate performance against established objectives have been identified, where suitable and applicable, to improve performance. Management review meeting minutes describe each objective, the monitoring and/or measurement(s) applied, and the frequency of measurement analysis. The Leadership and Management procedure provides details regarding responsibilities and authorities for reviewing the resulting performance information, for analyzing it, for reacting appropriately, and for reporting QMS performance to employees.

4.5.2. The application of performance monitoring and measurement at two levels reflects the original quality planning that resulted in the development of the QMS in two levels: the process level and the system level. (See Section 4.3 above, Quality Planning.)

4.5.3. Process Level

4.5.3.1. At the process level, attention is focused on ensuring conformity of the product and services to requirements, and to assure the effectiveness and efficiency of primary processes.

4.5.3.2. Suitable verification and/or measurements are applied to the product and service itself to ensure that product and service conformity has been demonstrated. Requirements to perform such verifications appear in procedures where they naturally occur at the appropriate stages in processing. Quality Control personnel's initials on Work Order Traveler records and SAE Quality Assurance Labels indicate the person authorizing release. This verification or measurement is not only an indication of product and service conformity, but also an indication of the effectiveness of the process to produce planned results. Controls relating to nonconforming outputs appear in the Nonconformity and Corrective Action procedure.

4.5.3.3. Suitable monitoring and/or measurement is/are also applied to each process itself, where applicable. At a minimum, each QMS process is monitored by internal audits, corrective action, and management review. As determined to be suitable and applicable, further monitoring and measurement of process effectiveness and/or efficiency will be established by Management, including any in-process measurements, as well as those applied to inputs or outputs. Monitoring or measurement indicators will be identified in the QMS Planning Tool and management review meeting minutes and will be measured, reported, analyzed and acted upon accordingly.

4.5.3.4. Whenever planned results are not achieved according to the results of monitoring or measurement, either at the process or at system level, correction and corrective actions are taken, as appropriate, to ensure conformity of the product and service. Process level information is analyzed and acted upon as it arises or becomes available, and periodically according to the discretion of Management. Results are recorded as required. Product release does not proceed until all planned arrangements have been satisfactorily completed, unless otherwise approved by Management.

4.5.4. System Level

4.5.4.1. At the system level, attention is focused on general performance—performance of the system of processes in aggregate.

4.5.4.2. Suitable measurements are applied to the QMS as a whole to evaluate its performance against the quality policy objectives established in management review meeting minutes. Internal and external measurements are applied, where feasible. For example, objectives derived from the quality policy have been established for customer satisfaction (see below). Appropriate system level information is analyzed and acted upon periodically as required by the management review process, and more frequently as circumstances demand. Results of system level review appear in meeting minutes.

4.5.4.3. As one measure of QMS performance, customer satisfaction is perhaps the most important. Accordingly, information regarding our customers' perception of our performance is determined by indicators or may be solicited by customer satisfaction surveys according to the Sales procedure and is analyzed according to the Leadership and Management procedure. Unsolicited feedback, including complaints and product returns, is also received, reviewed, and acted upon according to the Sales procedure.

On-time delivery and product conformity metrics are also in place to ensure customer satisfaction.

4.6. Continual Improvement

4.6.1. Through use of the quality policy, process and system level quality objectives and performance information, audit results, external provider performance analysis, corrective action and management review, SAE will continually improve QMS effectiveness and efficiency. See the Leadership and Management procedure.

4.6.2. Improvement is achieved anytime an increased ability to fulfill requirements is demonstrated by measurable results or quantifiable benefits (or estimates thereof).

4.6.3. When opportunities for improvement present themselves by whatever means, Management takes advantage of those opportunities by initiating activities to plan and implement the improvement. Improvement efforts are typically tracked on the Action Item Matrix worksheet in the QMS Planning Tool.

5. QMS Processes

5.1. Primary Processes

5.1.1. Sales

5.1.1.1. Generally, the objective of the Sales process is to pursue business opportunities in order to provide products and services that will satisfy customers. Inputs include customer requirements, which are typically communicated to the company in the form of customer requests for quotes (or for proposals) and awarded customer purchase orders. Customer requirements are reviewed to ensure they are clear and complete, and that SAE has the ability to meet them prior to their acceptance. Applicable statutory and regulatory requirements are also reviewed to ensure compliance can be achieved. If upon review BMK determines that some customer requirements cannot be met or can only partially be met, the President will negotiate a mutually acceptable requirement with the customer. BMK's process ensures that reviews for order acceptance are coordinated with applicable functions.

5.1.1.2. Sales activities transform the above inputs into their respective outputs: approved quotations and order confirmations. Before their approval or acceptance, the customer's requirements for the product and its timely delivery are verified to be clear and complete, including any requirements that might not have been stated by the customer but are necessary for the proper or safe functioning of the product. The President verifies the ability to meet such requirements before committing to supply products to the customer.

5.1.1.3. The Sales procedure also contains provisions for controlling product and service information, for handling inquiries, for reviewing customer purchase orders against any previously agreed requirements or quotations, as well as for reacting to change orders from customers and questions regarding order status.

5.1.1.4. Inputs to the Sales process also includes both solicited and unsolicited feedback regarding the customers' perception of the company's performance, based on the quality of the delivered products. Relevant information received is evaluated by Management and acted upon appropriately to ensure conformity of product to requirements and to ensure customer satisfaction. Customer satisfaction, on-time

delivery and quality are measured according to the Sales procedure and Leadership and Management procedure and is reviewed by Management accordingly.

5.1.1.5. Where actions are required based on performance information from customers, corrective actions are initiated, as appropriate, and are processed according to the Nonconformity and Corrective Action procedure.

5.1.2. Purchasing

5.1.2.1. Generally, the objective of the Purchasing process is to procure items and services needed to ensure producing products to quality requirements. More specifically, the objective of the Purchasing process is to ensure that purchasing information describes needed products and services in requisite detail, approved orders are submitted to reliable external providers, and that purchased items are verified to conform to requirements (including customer and/or any regulatory requirements). Inputs to the Purchasing process include purchasing needs arising in connection with products manufactured for customers and those arising from any QMS process, including management review, where resource needs are identified at both the process and system level. See the Purchasing procedure.

5.1.2.2. Potential external providers may also be viewed as an input to the Purchasing process. Possible suppliers, vendors, service providers, subcontractors, contract manufacturers, etc., are evaluated and selected as necessary according to their ability to meet purchasing requirements, and their impact on processing activities and the quality of finished product and services. Records of external approval status appear in the Supplier and Vendor Information spreadsheet.

5.1.2.3. External provider performance is monitored via records of vendor incidents recorded on the Supplier Incident Log. Such records include problems associated with quality, delivery, and returned purchased items. External provider performance is reviewed during management review and as any incidents occur.

5.1.2.4. The Purchasing process transforms identified purchasing needs into approved purchase orders which appropriately describe the needed products or services. This information also includes requirements for approval or acceptance of the product, as well as any required verification on the vendors' premises, or any requirements for the vendors' QMS, personnel, procedures, processes or equipment (which are not common). Additional flow down requirements are communicated to ensure that the entire supply chain is made aware of requirements, including where process validation is necessary. Approved purchasing documents are submitted to reliable external providers. Received items are verified against the purchasing documentation (see the Receiving and Shipping procedure).

5.1.2.5. Outsourced processes are subcontracted to approved external providers. Product resulting from outsourced manufacturing is received and verified before being released for use. Verification may include confirmation that supplied certificates demonstrate conformity to specified purchasing requirements. See the Receiving and Shipping procedure.

5.1.3. Receiving and Shipping

5.1.3.1. Generally, the objective of the Receiving process is to ensure that raw materials products meet applicable requirements before accepting them, and to prevent damage

or deterioration to raw materials and product during handling and storage while maintaining identification and traceability.

5.1.3.2. The Receiving portion of the Receiving and Shipping procedure describes methods for identifying product with respect to its status (and traceability, where required). The procedure addresses the treatment and use of customer property, as well as preservation methods used during handling, inspection and storage to ensure continuing conformity of product.

5.1.3.3. Incoming materials and goods are verified to conform to applicable purchasing requirements. Received items are verified through review against their associated packing lists and purchasing documentation.

5.1.3.4. Incoming items may also be customer property (for returned product). Customer property is appropriately identified and handled to prevent damage or loss. The customer is appropriately notified, and corrective action is taken should the customer's property become lost or damaged.

5.1.3.5. Only items passing receiving verification are accepted, barring authorized concessions or dispositions. Conforming items are stored appropriately in inventory while awaiting use or delivery to the customer. Nonconforming product is properly identified, evaluated and dispositioned as return to the vendor for replacement.

5.1.3.6. The Receiving and Shipping procedure also describes how inventory is controlled to maintain identification and to preserve conformity to requirements.

5.1.3.7. Generally, the objective of the Shipping process is to deliver acceptable products to the customer. Another objective is to ensure the products are adequately protected during transport. Prior to packaging, parts are cleaned and marked, if required, to customers' specifications.

5.1.3.8. The Receiving and Shipping procedure describes requirements for preparing finished products for delivery. The procedure addresses preservation methods used during packaging and shipment to ensure continuing conformity of product. Product is adequately packaged to preserve conformance to requirements and to prevent damage or deterioration during transport.

5.1.4. Production

5.1.4.1. Generally, the objective of the Production process is to manufacture products meeting customer requirements. More specifically, the objective of the process is to perform realization activities in a controlled manner to ensure that the resulting product is effective in meeting requirements. Inputs to the Production process include customers' drawings which specify product requirements and acceptance criteria. Outputs include product that meets all design and development requirements and regulatory requirements, and production and inspection records.

5.1.4.2. The Production procedure describes methods for identifying product with respect to its inspection status and traceability (where required). Methods used include reference to the products' part number, its physical appearance, its location, etc. The Production procedure also addresses the treatment and use of customer property, as well as preservation methods used during handling, inspection and storage to ensure continuing conformity of product.

5.1.4.3. Planning for Production consists of determining necessary equipment, manufacturing methods, documented information, etc. Customers' drawings used during production contain verification or inspection requirements and acceptance criteria associated with the product. Verifications demonstrating conformity of product occur at appropriate points during processing.

5.1.4.4. Competent personnel carry out production activities using suitable equipment and according to work instructions to which they have been trained. Product is not released for shipping activities until inspection is complete and recorded on the associated inspection records and Travelers.

5.1.4.5. Nonconforming output is properly identified and controlled in accordance with the Nonconformity, Corrective Action and Improvement procedure.

5.1.4.6. Repair maintenance and preventive maintenance of equipment used in Production is performed as necessary in accordance with the Production procedure. Calibrated equipment used during production to demonstrate conformity to requirements is controlled according to the Calibration procedure.

5.2. Support Processes

5.2.1. Training and Competence

5.2.1.1. Training and Competence supports all QMS processes (both primary and support). As a support process, the objective of training is to ensure that competent personnel perform QMS processes (i.e., work that affects quality). The Training and Competence process ensures that competency requirements are identified and that personnel are evaluated based upon the appropriate education, skills, experience and training required for each position affecting quality.

5.2.1.2. Training is provided as needed, the effectiveness of which is evaluated to verify competence before assigning work. A training record exists for each employee to demonstrate that employee's competence to perform assigned work. Training records also identify where further training needs have been identified for employees, as applicable. See the Training and Competence procedure.

5.2.2. Documented Information

5.2.2.1. The Documented Information process supports all QMS processes. The objective of documented information that is maintained is to ensure that legible, approve documentation is available to employees when and where it is needed in order to perform their assigned activities correctly. The procedure describes how such documentation is initially approved and how it is re-approved after being updated, and how the most current version of any QMS documentation is determined. The procedure also describes treatment of documents originating externally.

5.2.2.2. Controlling documented information ensures that only approved, current documentation is used, and that obsolete documentation is removed from use.

5.2.2.3. The objective of documented information that is retained (records) is to ensure that records of processing activities are maintained as long as they are useful and/or required. Such records demonstrate the effective operation of the QMS and conformity to applicable requirements (including any specified by customers and/or by regulatory agencies). Management establishes retention periods. Records control ensures that quality records are appropriately stored so to be protected from loss, damage and

deterioration, that they are readily identifiable and retrievable when they are needed, and that they are disposed of properly once their usefulness has expired. The Record Retention Matrix specifies the requirements for retaining records: their storage and protection, their retrieval or filing method, their retention periods and their method of disposal. See the Documented Information procedure.

5.2.3. Nonconformity, Corrective Action and Improvement

5.2.3.1. Nonconformity, Corrective Action and Improvement supports all QMS processes and improvement activities. Nonconforming outputs and nonconformities are corrected and controlled, and corrective actions taken in an effort to improve performance generally result in a corrective action. However, improvements may be identified and acted upon independently of corrective actions.

5.2.3.2. As a support process, the objective of the Nonconformity, Corrective Action and Improvement process is to:

a) Identify and correct nonconforming outputs to prevent unintended use or delivery to the customer as applicable,

b) Identify systemic or process-related problems or undesirable situations, to determine the cause(s), and to take action to address those causes so that they do not recur or occur elsewhere.

5.2.3.3. Records describing nonconforming outputs and the resulting actions are documented on the individual Corrective Action Reports.

5.2.3.4. Requests and needs for corrective action are processed using the Corrective Action Log. Once closed, the corrective action records provide evidence of actions taken and verification of their effectiveness.

5.2.3.5. Appropriate corrective actions are taken to eliminate the causes of existing problems or nonconformities in order to prevent their recurrence or occurrence elsewhere. Error-proofing methods are employed wherever applicable. Corrective actions are taken in response to information arising from audit results, customer feedback or complaints, vendor performance data, performance information regarding product and service nonconformity, process monitoring and measurement results, etc.

5.2.3.6. Should corrective actions prove ineffective; alternative solutions will be evaluated and applied until the issue is resolved. See the Nonconformity, Corrective Action and Improvement procedure.

5.2.4. Internal Audits

5.2.4.1. Internal Audits support all QMS processes. As a support process, the objective of Internal Audits is to monitor processing activities at planned intervals to ensure their effective implementation and upkeep, and to ensure that they comply with the planned arrangements described by QMS documentation, as well as to confirm their continuing compliance with the requirements of ISO 9001.

5.2.4.2. Internal audits verify that working practice is conducted in accordance with the quality policy, procedures, and provisions in this manual, ensuring that issues regarding compliance are resolved appropriately. All QMS processes are audited internally by either internal resources or contract auditors. Internal audits are scheduled according to the importance of the activities being audited according to the requirements of the

Internal Audit Schedule. Audits are conducted by trained, impartial Auditors, according to the instructions, scope, criteria and any specific methods appearing on Internal Audit Report forms. See the Internal Audits procedure.

5.2.4.3. Where working practice fails to conform to planned arrangements, or when problems or opportunities for improvement are discovered, auditors generate findings, which are recorded on the Internal Audit Report.

5.2.4.4. Upon completion of an audit, auditors summarize their findings and conclusions on the associated Internal Audit Report form, and submit the report and findings to Management, who take timely action. Corrective actions arising from audits will be processed according to the Nonconformity and Corrective Action procedure to ensure that effective action is taken in a timely manner. Internal audits are conducted, reported and the results acted upon according to the Internal Audits, Nonconformity, Corrective Action and Improvement, and Leadership and Management procedures.

5.2.5. Calibration

5.2.5.1. Calibration supports processes involving measurement accuracy and traceability. In support of these processes, the objective of Calibration is to ensure that suitable, accurate measuring equipment is used to demonstrate conformity of product to applicable requirements. The Calibration process ensures that measuring equipment is selected and used in a manner consistent with measuring requirements, and that such equipment is calibrated or verified periodically (or before use) to ensure their continuing fitness for use, in order to impart confidence that the instruments are suitable in their precision and that the resulting measurements are accurate.

5.2.5.2. The Calibration procedure ensures that calibration results bear traceability to international or national standards. The procedure also ensures that such equipment is appropriately identified, handled, stored and safeguarded to prevent damage and deterioration. Calibrations and verifications are conducted according to the Calibration Recall Software which indicates when calibrations and verifications are due, while results and historical performance data are recorded in each instrument's calibration record in the Calibration Recall Software. Should any monitoring or measurement software be introduced to the QMS, it will be treated as a calibrated or verified instrument and will be confirmed and reconfirmed as necessary to ensure its continuing suitability.

5.2.5.3. When equipment is found to be out of calibration, the Director, QA will investigate the impact of the potentially errant measurements on product previously measured with the equipment to ensure that the impact is known, that it is corrected or otherwise resolved, and that all affected parties are notified, as appropriate. Unsuitable equipment is withdrawn from use, or their use is limited to be appropriate for the measurements being carried out. See the Calibration procedure.

5.2.6. Leadership and Management

5.2.6.1. The Leadership and Management procedure describes how the QMS Planning Tool is used to plan and monitor QMS requirements, issues, and strategic plans to ensure the QMS is aligned with the SAE's purpose as described in section 4.3 above

5.2.6.2. Risk management is also described in the procedure to ensure that issues that can impact the achievement of planned results and meeting customer and interested party requirements are addressed.

5.2.6.3. The Leadership and Management procedure also describes how performance data from various sources is analyzed and acted upon, including information relating to customer satisfaction, quality (i.e. conformance to requirements), process or product and service performance trends suggesting need for improvement, and external provider performance. These measurements are analyzed and acted upon in an effort to improve performance.

5.2.6.4. Inputs to management review meetings include audit results, customer feedback, information regarding nonconformities and corrective actions, and actions decided during previous Management reviews, external provider performance information, internal performance information regarding product and service conformity and process monitoring and measurement, any identified improvement opportunities or recommendations, and any identified internal or external changes that could impact the QMS.

5.2.6.5. Management periodically reviews the QMS as a whole to determine its effectiveness in meeting objectives and applicable requirements, including those of our customers and those of ISO 9001. Management also determines whether the QMS, the quality policy and quality objectives are still suitable and adequate for the company, according to the Management Review Meeting Minutes, which when complete, stands as the record of review. Where actions are required based on information from whatever source, actions are initiated. See the Leadership and Management procedure.

5.2.6.6. Once performance levels are analyzed and QMS effectiveness has been determined, performance information is communicated to employees, so they understand how their performance affects the achievement of established objectives. Such communication occurs through verbal reporting during meetings or on an individual basis. Performance results may also be posted in a conspicuous location.

6. Change History

Rev Date	Description	Approved
080118	Initial release. Written to meet the requirements of ISO 9001:2008 and ISO 9001:2015. Section highlighted in yellow related to ISO 9001:2008 are to be removed following Transition audit.	G. Warner