QUALITY MANAGEMENT SYSTEM MANUAL

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Approved by:

President

Contents

Q01 Document Control

Document

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Authorization

Authorized By: Wesley Smith

Position: President

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Q02 Document Amendments

All copies of this Quality Management Systems Manual (QMSM) must be kept under strict control to prevent the system from becoming unreliable. The following controls will ensure that the system remains current and valid.

1. All copies of the manual will be clearly numbered, and the Holder recorded.

2. Each page in the manual will carry its own number.

3. The Management Representative will be responsible for all revisions and additions being recorded.

4. Changes can be suggested by any Employee but must receive signed approval before being entered into the QMSM.

5. All changes must be recorded on the Amendments Table below and appropriate pages in each QMSM changed. Significant changes will be shaded to make them easy to identify. (Where existing text is reworded or reorganized in the document, these changes will not be shaded.)

Amendments Table

Doc. No.	Page No.	Issue	Date	Description of change	Authorization
QMSM	All	1.0	TBD	Initial Release	

Q03 Company Organization Chart

Wesley Smith – President
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Q04 Quality Management System

4. Context of the organization

4.1 Understanding the Organization and its Context

We have determined the relevant external and internal issues that affect our ability to achieve the intended outcomes of our management system. We have considered the full business environment, the key drivers and trends having impact on the objectives of the organization and the relationship and values of external stakeholders. We take into consideration regulatory requirements, including requirements regarding climate change. Details of the context of our organization are in:

See document – QMS REC 09 Business Context Development

4.2 Understanding the Needs and Expectations of Interested Parties

We have identified the interested parties and their requirements with the emphasis being on quality. We have included a process to determine any legal requirements relating to activities, products that are relevant to the scope of our management system.

See document – QMS REC 09 Business Context Development

4.3 Determining the Scope of the Quality Management System

We have determined the boundaries and applicability of our management system and have considered the issues identified in Clause 4.1 and 4.2 (above) as well as those that relate to our products when establishing the scope.

See document – QMS PRO 01 Management System Scope

4.4 Quality Management System and its processes (QMS)

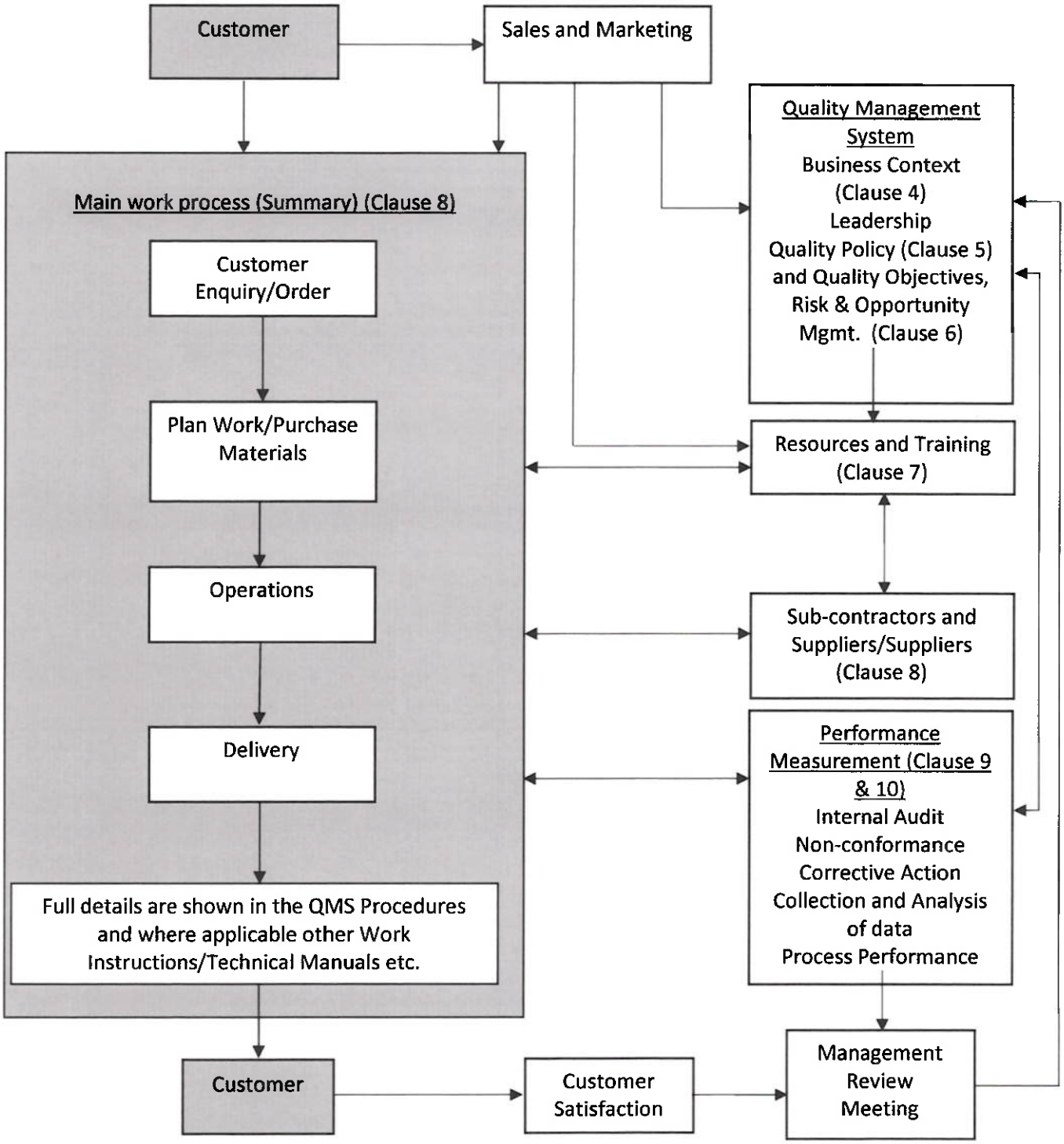
We have established and implemented and will look to maintain and continually improve our quality management system, including the processes and their interactions needed to meet the requirements of the international standard.

To deliver the requirements, we have identified:

- the processes needed for the implementation, operation, and maintenance of the management system along with opportunities for its improvement and their application throughout the organization.
- the inputs required and outputs expected from these processes.
- the sequence and interaction of these processes.
- criteria and methods needed to ensure that both the operation and control of these processes are effective.
- the availability of resources and information necessary to support the operation and monitoring of these processes.
- the risks and opportunities within the management system and how to plan to address them.
- the monitoring, measuring, and analyzing of these processes, and implement actions necessary to achieve planned results and continual improvement.

Appropriate documented information is maintained to support these processes and is retained as records to demonstrate that all processes are working as planned.

QMS REC 10 Process Diagram:



5. Leadership

5.1 Leadership and Commitment

5.1.1 General

Our Top management have demonstrated leadership and commitment with respect to our QMS by taking accountability of the effectiveness of the QMS; by establishing a quality policy and quality objectives that are compatible with the direction of the organization; by ensuring that both policy and objectives are communicated, understood and applied within the organization; by ensuring integration of QMS requirements into the organization's business processes and by promoting awareness of a process approach and risk based thinking.

In addition, our Top Management have provided the necessary resources for the QMS; communicated the importance of effective quality management and of conforming to QMS requirements; ensuring that the QMS achieves intended results; engaging with, directing, and supporting persons to contribute to the effectiveness of the QMS; promote improvement and support other members of the management team to demonstrate their leadership as it applies to their area of responsibility.

5.1.2 Customer Focus

As an organization, we strive to meet our clients' expectations; our management has demonstrated their leadership and commitment by ensuring that clients' requirements and applicable regulatory and statutory requirements are met; that risks and opportunities that could affect our products and services have been addressed and that our focus is on consistently providing client satisfaction.

5.2 Policy

Our Top Management has developed a quality policy that is in line with the requirements of the standard. The Policy is available as documented information, is communicated throughout the organization and is also available to interested parties, as appropriate.

See Document – QMS POL 01 Quality Policy

5.3 Organizational Roles, Responsibilities and Authorities

Our Top management will ensure that the responsibilities and authorities for relevant roles are assigned and communicated throughout the organization. The organization has identified, documented, and communicated the roles, responsibilities, and authorities of those involved in the management system and their interrelationships within the organization.

See Document – QMS REC 08 Roles & Responsibilities
QMS REC 11 Job Description

6. Planning

6.1 Actions to Address Risks and Opportunities

We have considered the issues detailed in clause 4.1 and 4.2 of this document and have determined the risks and opportunities that need to be addressed to assure the QMS can achieve its intended outcomes; that we prevent or reduce undesired effects and achieve continual improvement.

We have put a plan in place to address these risks and opportunities and a plan to integrate and implement these actions in the QMS and evaluate their effectiveness. We have produced a risk assessment register to show what has been achieved.

See document – QMS PRO 02 Risk Assessment Procedure

6.2 Quality Objectives and Planning to achieve them

We have established quality objectives at various levels throughout the organization in line with the requirements of ISO9001:2015 Clauses 6.2.1 and 6.2.2; a document has been produced detailing these objectives and the procedure around establishing them.

See document – QMS PRO 11 Planning to Achieve Quality Objectives

6.3 Planning of Changes

If we make changes to our QMS they would be carried out in a planned and systematic manner. We will consider the purpose of any change, its potential consequences, the integrity of the QMS, the availability of resources and the allocation or reallocation of responsibilities and authorities.

See document – QMS PRC 01 Change Management Process

7. Support

7.1 Resources

7.1.1 General

We have determined and provided the resources needed for the establishment, implementation, maintenance, and continual improvement of our QMS. We have considered the capabilities of our existing resources and what we need to obtain from external providers.

See Document: QMS PRO 03 Monitoring Measuring Resources

7.1.2 People

Those resources include people who have the necessary skills and competencies to effectively operate our QMS and to meet and exceed our clients' expectations. Also see Clause 7.2.

7.1.3 Infrastructure

We have provided the infrastructure determined necessary for the provision of our processes and conformity of our products.

7.1.4 Environment for the Operation of Processes

We have provided the environment determined necessary for the provision of our processes and conformity of our products.

7.1.5 Monitoring and Measuring Resources

We have determined that we need to use measuring and monitoring resources for evidence of conformity for our products and have created specific documented information detailing how we have approached this requirement.

See document – QMS PRO 03 Measuring Monitoring Resources

7.1.6 Organizational Knowledge

We have determined the knowledge necessary to operate our processes when achieving conformity of our products and services. We have systems in place to address any changes to our needs and possible trends that come up from time to time. The knowledge is in the form of documented information and is available to those who require it.

7.2 Competence

We have determined the competence of people doing work under our control that affects performance to ensure that these people are competent based on appropriate education,

training or experience and where applicable, take actions to acquire the necessary competence and evaluate the effectiveness of the actions taken.

See document – QMS REC 16 Skills Competency Matrix
QMS REC 13 Training Record

7.3 Awareness

We have ensured that people doing work under our control are aware of our policies; our quality objectives relevant to them; their contribution to the effectiveness of the system and the implications of not conforming to the QMS requirements.

See document – QMS REC 13 Training Record

7.4 Communication

We have determined the need for internal and external communications relevant to the system including on what, when, with whom, how and who would communicate.

See document - QMS PLN 01 Communication Plan

7.5 Documented Information

We have written policies and procedures as appropriate to meet the requirements of our QMS and the ISO9001:2015 standard. Details of how we produce and control our documented information are given in M06.

See document – QMS PRO 04 Document Control & Records

8. Operation

8.1 Operational Planning and Control

We have planned, implemented, and controlled processes needed to meet requirements for the provision of our products, and to implement the actions determined in clause **6.1** of this document by determining the requirements of our products, establishing criteria for those processes and for the acceptance of our products. We have also determined the resources needed to achieve conformity of our products and by implementing control of the processes in accordance with the detailed criteria.

We keep documented information to the extent necessary to have confidence that the processes have been carried out as planned and that demonstrate the conformity of our products.

We shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects as necessary. We shall ensure that outsourced processes are also controlled.

See document – QMS PRO 06 Production and Service Provision

8.2 Requirements for Products and Services

8.2.1 Customer Communication

We communicate with clients where necessary in relation to information related to our products and services, enquiries, contracts, or order handling including changes, customer property, obtaining their feedback, including complaints and specific contingency actions where appropriate.

8.2.2 Determination of Requirements Related to Products and Services

When determining the requirements for our products and services offered to potential clients, we have ensured that applicable regulatory and statutory requirements have been defined, that we can meet those requirements and that we can substantiate any claim made for our products and services.

8.2.3 Review of Requirements Related to Products and Services

We review our clients' requirements, including those for delivery and post-delivery activities and any statutory and regulatory requirement applicable to the product being provided. We also review those requirements not stated by the client, when known, plus any contract or order requirements that are different from the original request.

We conduct this review prior to our commitment to supply our products and services; we always provide a documented confirmation of the order, even if the client has not; details of all orders are recorded on in house Order Processing system.

Where requirements change, we ensure that all relevant documentation is amended and that personnel are made aware prior to delivery.

8.2.4 Changes to requirements for products and services

We will ensure that when changes are made to our products relevant persons are made aware and relevant documentation is amended to reflect those changes made.

8.3 Design and Development of Products and Services

We have looked at the requirements of this clause in the standard and have determined that they are not applicable to the scope of our management system.

8.4 Control of Externally Provided Processes, Products and Services

We have produced a procedure which details how our organization would deal with the control of externally provided products and services.

See document – QMS PRO 05 Control of Externally provided products and services

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

We have implemented controlled conditions for the production and service provision, including delivery and post-delivery activities in line with the requirements of Clause 8.5.1 of the ISO9001: 2015 quality management system standard.

8.5.2 Identification and Traceability

Where necessary we have introduced a system to uniquely identify our products for the purposes of traceability. We identify the status of our processed outputs with respect to monitoring and measurement requirements throughout the provision of our products. We retain documented information appropriate to maintaining identification and traceability.

8.5.3 Property belonging to Customers or External Providers

We exercise due care and attention when dealing with property belonging to external providers (including clients). We report any defect, damage, or loss to the external provider as soon as it has been identified by our personnel.

8.5.4 Preservation

We ensure the preservation of our products to the extent necessary to maintain their conformity throughout the production process.

8.5.5 Post-delivery Activities

We ensure that where applicable we meet the requirements for post-delivery activities associated with our products to the extent that we have considered the risks associated with the

products, the nature of use and lifetime of the products, customer feedback and statutory and regulatory requirements.

8.5.6 Control of Changes

We review and control changes necessary for the production and service provision to ensure continued conformity of our products. We keep documented records of any such changes using form R14.

See document – QMS PRO 06 Production and Service Provision

8.6 Release of Products and Services

We have implemented arrangements at appropriate stages of production or service provision to verify that product requirements have been met; evidence of such acceptance criteria are recorded in the internal Order Processing system.

Products will not be released to our clients until the verification arrangements have been met; the exception is when authorized by QMSR / Production Manager or by the client themselves. Appropriate records of who authorized the release are recorded in the internal Order Processing system.

8.7 Control of Nonconforming Outputs

We have produced a procedure which details how our organization would deal with the control of nonconforming process outputs, products, and services.

See document – QMS PRO 07 Non-conformance & Corrective Action

9. Evaluation

9.1 Monitoring, measurement, analysis, and evaluation

9.1.1 General

We have determined what needs to be monitored and measured; the methods for monitoring, measurement, analysis, and evaluation, as applicable, to ensure valid results; when the monitoring and measuring shall be performed and when the results from monitoring and measurement shall be analyzed and evaluated.

We retain documented information on the results of such monitoring and measurement to enable us to evaluate the effectiveness of our QMS.

See document – QMS PRO 08 Monitoring and Measurement Results

9.1.2 Customer Satisfaction

We have determined the methods for obtaining information regarding our clients' perception of our organization in terms of meeting or exceeding their requirements in the provision of our products and services. The information gathered is reviewed as part of the Management Review process.

See document – QMS PRO 08 Monitoring and Measurement Results

9.1.3 Analysis and Evaluation

We analyze and evaluate data gathered as part of our monitoring and measuring activities and the results are used as part of our Management Review process.

See document – QMS PRO 08 Monitoring and Measurement Results

9.2 Internal Audit

We conduct internal audits at planned intervals to provide information on whether our QMS conforms to our requirements, to the requirements of ISO9001:2015 Quality Management System standard and is effectively implemented and maintained; it also takes into consideration the importance of the processes concerned. We have implemented a procedure that covers in detail the process surrounding the internal audit process.

See document – QMS PRO 09 Internal Audit Procedure

9.3 Management Review

Our Top management reviews the organization's QMS at planned intervals, at least once every 12 months, to ensure its continuing suitability, adequacy, and effectiveness. Each review will take into consideration the status of actions from any previous meetings and any changes in internal or external issues relevant to our QMS and performance information, including trends and indicators as detailed in ISO 9001:2015 Clause 9.3.1 and 9.3.2.

Information relating to each of these meetings is recorded using document QMS REC 06 Management Review Agenda and Minutes

See document – QMS PRO 10 Management Review Procedure

10 Improvements

10.1 General

We have determined and shall select such opportunities as necessary for improving our clients' requirements and satisfaction. This will include improving our products, correcting, preventing, or reducing undesired effects improving the performance and effectiveness of our QMS.

10.2 Nonconformity and Corrective Action

When non-conformity occurs, we shall react to the nonconformity and take action to control and correct it and then deal with the consequences. We will evaluate the need for action to eliminate the causes of the nonconformity, in order that it does not recur or occur elsewhere in the organization. We will implement the actions required and review the effectiveness of any corrective action taken, update risks and opportunities determined during planning (if necessary) and make changes to the QMS, where necessary.

We record all nonconformities, actions taken and the results of any corrective action using the appropriate documentation.

See documents – QMS PRO 07 Non-conformance and Corrective Action

10.3 Continual Improvement

We shall continually improve the suitability, adequacy, and effectiveness of our QMS. We consider the results of analysis and evaluation and the outputs from management review to determine if there are needs or opportunities that could be addressed as part of our continual improvement.

Q05 Document Register

Reference	Title	Revision	Date	Authority
QMS POL 01	Quality Policy	1	TBD	QMSR
QMS PLN 01	Communication Plan	1	TBD	QMSR
QMS PRC 01	Change Management Process	1	TBD	QMSR
QMS PRO 01	Scope of QMS	1	TBD	QMSR
QMS PRO 02	Risk Assessment Procedure	1	TBD	QMSR
QMS PRO 11	Planning to Achieve Quality Objectives	1	TBD	QMSR
QMS PRO 03	Monitoring and Measuring Resources	1	TBD	QMSR
QMS PRO 05	Document Control & Records	1	TBD	QMSR
QMS PRO 04	Control of Externally Provided P & S	1	TBD	QMSR
QMS PRO 06	Production & Service Provision	1	TBD	QMSR
QMS PRO 07	Non-conformance & Corrective Action	1	TBD	QMSR
QMS PRO 08	Monitoring & Measurement Results	1	TBD	QMSR
QMS PRO 09	Internal Audit Procedure	1	TBD	QMSR
QMS PRO 10	Management Review Procedure	1	TBD	QMSR
Reference	**Title**	**Issue No.**		**Authority**
QMS REC 01	Risk & Opportunity Register	1	TBD	QMSR
QMS REC 02	Quality Objectives	1	TBD	QMSR
QMS REC 03	Document Change Request	1	TBD	QMSR

QMS REC 04	Internal Audit Schedule	1	TBD	QMSR
QMS REC 05	Internal Audit Report	1	TBD	QMSR
QMS REC 06	Management Review Agenda & Minutes	1	TBD	QMSR
QMS REC 07	Non-conformance Report and Corrective Action Report	1	TBD	QMSR
QMS REC 09	Business Context of the Organization	1	TBD	QMSR
QMS REC 10	QMS Process Model	1	TBD	QMSR
QMS REC 11	Job Description	1	TBD	QMSR
QMS REC 17	Calibration Register	1	TBD	QMSR
QMS REC 13	Training Record	1	TBD	QMSR
QMS REC 14	External Providers' Evaluation Results	1	TBD	QMSR
QMS REC 16	Skills Competence Matrix	1	TBD	QMSR
QMS REC 12	Complaints Form	1	TBD	QMSR