CARTER MACHINERY
FLUID ANALYSIS LAB

ISO 9001:2015
Quality Management System

Owner: Mike Dudley

Contents

Introduction

.01 General

This Quality Manual demonstrates and documents Carter Machinery Fluid Analysis Lab's (hence forth referred to as Fluid Analysis Lab) commitment to maintaining a high-level of quality and strong customer service within an environment that has safety as a first priority, is focused on the customers, and fosters continual improvement.

This Quality Manual specifies requirements that the Fluid Analysis Lab uses to address customer satisfaction, to meet customer and applicable regulatory and statutory requirements and to meet ISO 9001:2015 requirements and is supported by additional procedures where necessary. The quality management principles stated in ISO 9000, and ISO 9004, have been taken into consideration during the development of this Quality Policy Manual. This Quality Manual specifies the general requirements for the Fluid Analysis Lab's competence towards a management system for quality.

1 Scope

This Quality Manual specifies requirements for a quality management system where the Fluid Analysis Lab:

a) Needs to demonstrate its ability to consistently provide product and services that meet customer and applicable statutory and regulatory requirements, and

b) Aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

All the requirements of this ISO 9001:2015 are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.

4 Context of the Organization

4.1 Understanding the Organization and its Context

The Fluid Analysis Lab has determined external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system. The Fluid Analysis Lab monitors and reviews information about these external and internal issues. (See Fig 1)

Internal Issues	External Issues
Employee Competency	Customer Satisfaction
Organizational Performance	Markets & Competitors
Quality	Regulatory & Statutory
Capacity	Supplier Performance
Communication	Overall Economic Climate

Infrastructure	Technology Advances
Internal Politics	Cultural & Social
Intellectual Property	Health, Safety and Environmental Requirements
Workforce Safety	Contracts / Agreements
Workforce Wellness	
Work-Life Balance	
Continual Improvement	
Business Continuity	
Market Share	
CAT Standardization	

Fig 1

4.2 Understanding the Needs and Expectations of Interested Parties

Due to their effect or potential effect on the Fluid Analysis Lab's ability to consistently provide services that meet customer and applicable statutory and regulatory requirements, The Fluid Analysis Lab determined:

a) The interested parties that are relevant to the quality management system;

b) The requirements of these interested parties that are relevant to the quality management system.

The Fluid Analysis Lab monitors and reviews the information about these interested parties and their relevant requirements. (See Fig 2)

Interested Parties	Needs and Expectations
External Providers (External)	Prompt Payment, work relationship
Accounting (Internal)	Accurate sales data and accurate financial reporting
Inventory Control (Internal)	Accurate parts counts to ensure availability
Information systems (Internal)	Equipment, network administrators, business applications
Sales (Internal)	Product that meets intended purpose of adding value and driving loyalty
Customers	Value for money, accurate results, fast processing, effective communication, technical support, supply continuity
Shop and Field Service (Internal)	Fast processing, accurate results, effective communication.
Caterpillar	Accurate results for data analysis and product development.
Local, State and Federal Agencies	Adherence to standards and regulations.
Management (Internal)	Good financial performance, business strategy, continued growth, safety.
Employees (Internal)	Good and safe work environment, job security, recognition and award, training, effective communication, advancement.

Marketing (Internal)	Correct product branding, accurate product information.
Competitors	To make a profit, increase market share
Management	Safety, quality staff, increasing profits, increased market share.
Media	Access to information that may impact any of their interested parties.

Fig 2

4.3 Determining the Scope of the Quality Management System

The Fluid Analysis Lab is a department of Carter Machinery Inc. The product of the Fluid Analysis Lab is the service of providing testing, analysis and interpretation of oil, coolant, and fuel samples.

The Fluid Analysis Lab has determined the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, the Fluid Analysis Lab considered:

a) The external and internal issues referred to in 4.1; (see Fig 1)

b) The requirements of relevant interested parties referred to in 4.2; (see Fig 2)

c) The services of the Fluid Analysis Lab

The scope of the Fluid Analysis Lab's quality management system is available and maintained as documented information. The scope states the services covered and provides justification for any requirements that the Fluid Analysis Lab has determined is not applicable to the scope of its quality management system.

Conformity to ISO 9001 is only claimed if the requirements determined as not being applicable do not affect the Fluid Analysis Lab's ability to ensure the conformity of its services and the enhancement of customer satisfaction.

Scope of Registration

The Scope associated with the Fluid Analysis Lab activities and registration is:

The testing, analysis and interpretation of oil, coolant and fuel samples.

The Fluid Lab deems the following NOT APPLICABLE and therefore EXCLUDES- **Clause 8.3**- Design and development because the Fluid Analysis Lab does not design and develop products or testing services for customers.

4.4 Quality Management System and its Processes

4.4.1 The Fluid Analysis Lab has established, implemented, maintains, and continually improves a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.
The Fluid Analysis Lab has determined the processes needed for the quality management system and their application throughout the Fluid Analysis Lab, and

a) Determined the inputs required and the outputs expected from these processes; (see Fig 4, oil; Fig 5, coolant and Fig 6, fuel process flows)

b) Determined the sequence and interaction of these processes; (see overall process map, Fig 3)

c) Determined and applied the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes (see Objective Matrix)

d) Determined the resources needed for these processes and ensure their availability;

e) Assigns the responsibilities and authorities for these processes; (see Org Chart- Fig 7, job descriptions)

f) Addresses the risks and opportunities as determined in accordance with the requirements of 6.1; (see Risk Chart)

g) Evaluates these processes and implement any changes needed to ensure that these processes achieve their intended results. (see Internal Audit, Corrective action plan)

h) Improves the processes and the quality management system. (see continual improvement process)

4.4.2 To the extent necessary, The Fluid Analysis Lab:

a) Maintains documented information to support the operation of its processes

b) Retain documented information to have confidence that the processes are being carried out as planned (See Master list of Documents).

Overall Process Map

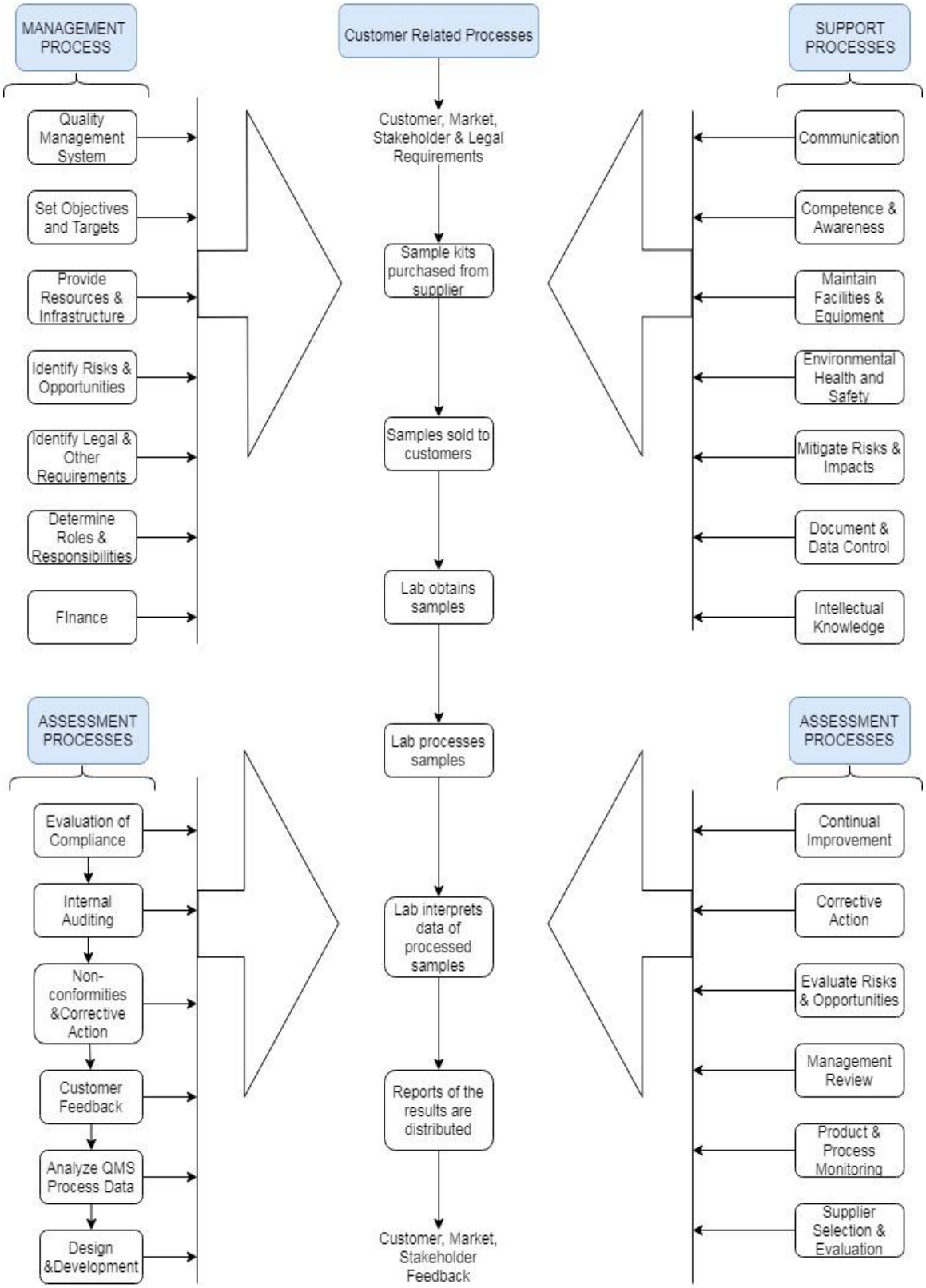

Fig 3

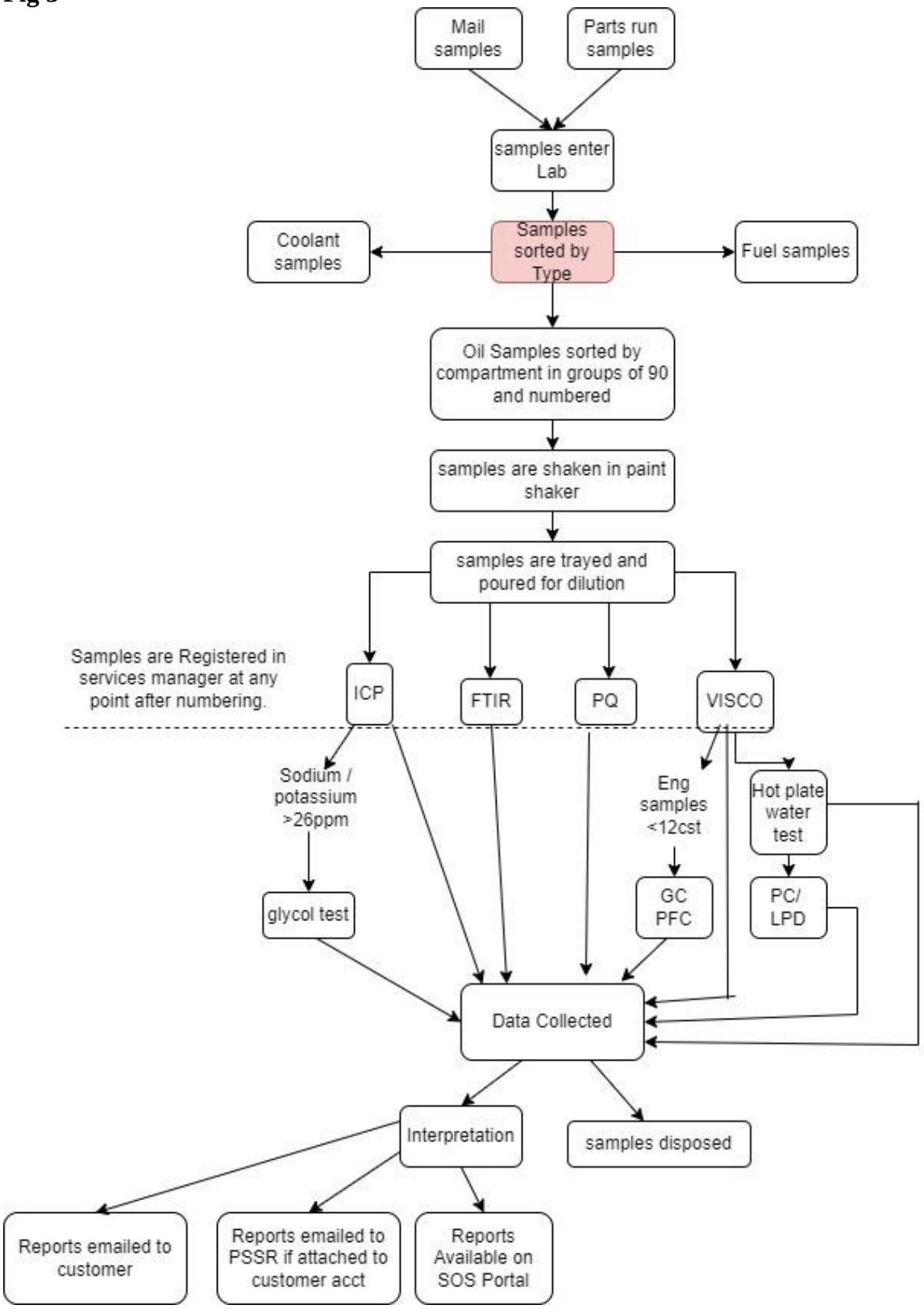

Fig 4

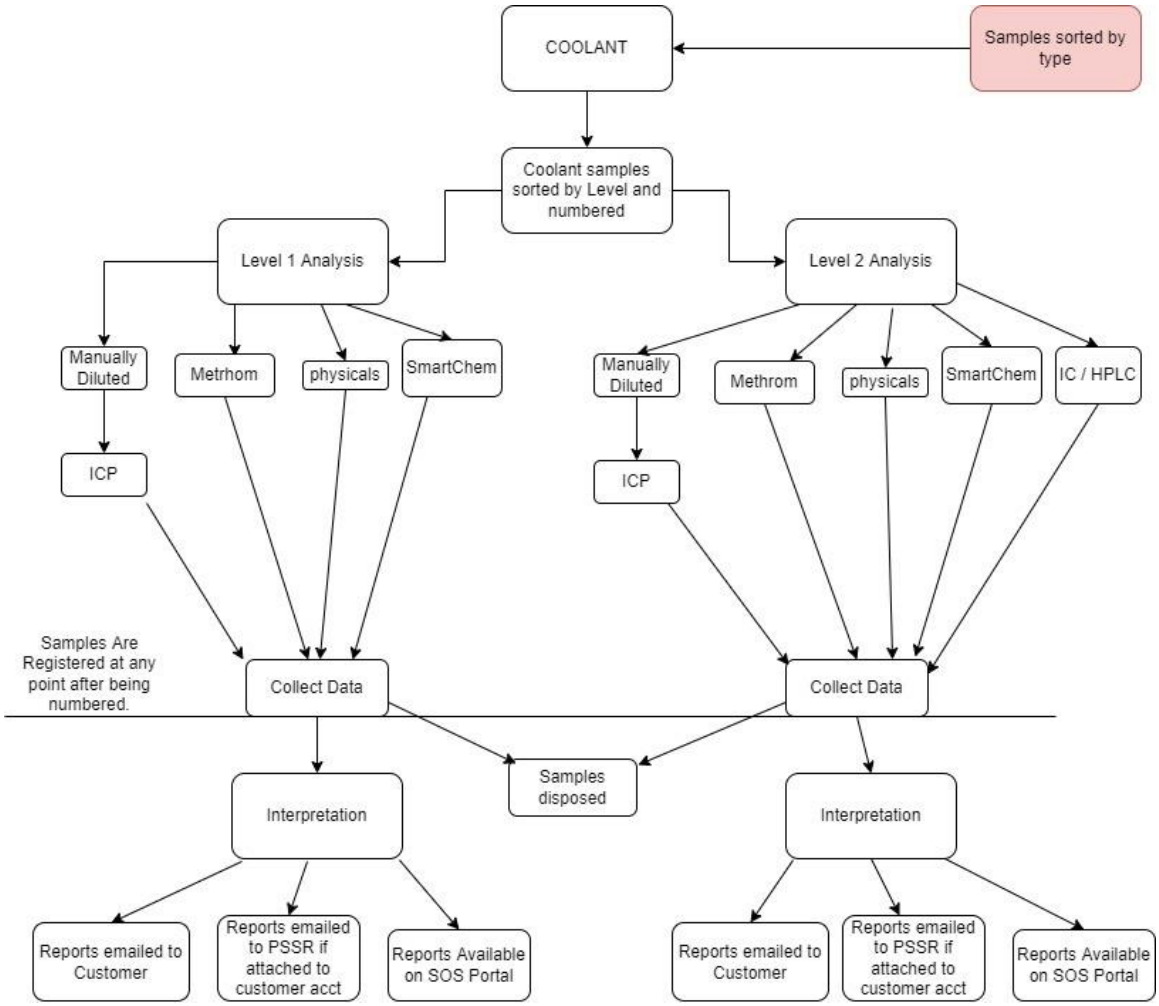

Fig 5

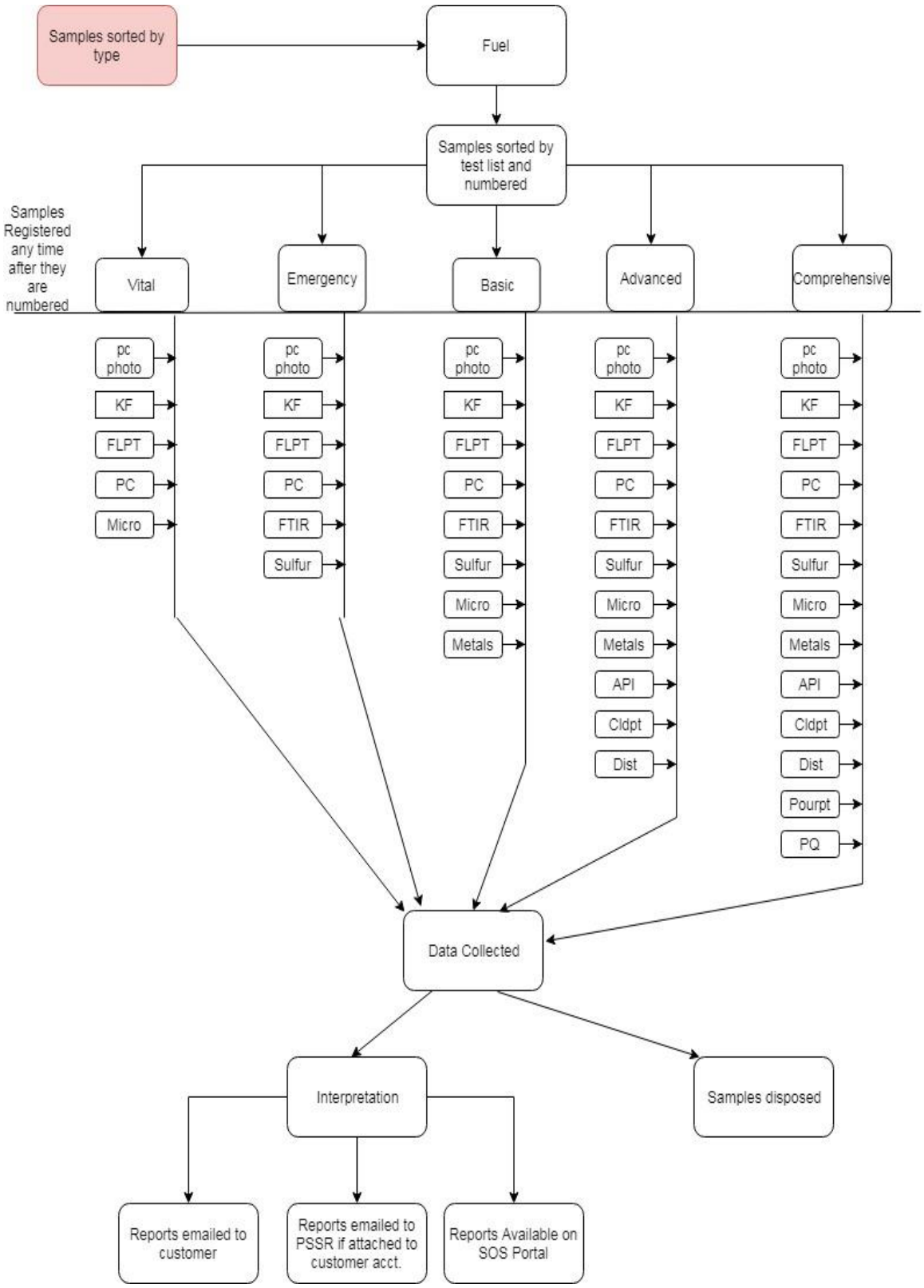

Fig 6

5 Leadership

5.1 Leadership and Commitment

5.1.1 General

Top management demonstrates leadership and commitment with respect to the quality Management system by:

a) Taking accountability for the effectiveness of the quality management system; (See Management review logs)

b) Ensuring that the quality policy and quality objectiveness are established for the quality management system and are compatible with the context and strategic direction of the Fluid Analysis Lab; See Quality Policy

c) Ensuring the integration of the quality management system requirements into the Fluid Analysis Lab's business process; (See Overall Process Map-Fig 3)

d) Promoting the use of the process approach and risk-based thinking; (See Risk Chart)

e) Ensuring that the resources needed for the quality management system are available; Human Resources and Facilities – hiring process/job description – evidence of training- etc.. (See master document list for supporting evidence)

f) Communicating the importance of effective quality management and of conforming to the quality management system requirements; (i.e. C.I. Meetings)

g) Ensuring that the quality management system achieves its intended results; (See Management Review, Objective Matrix and Internal audit program)

h) Engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;

i) Promoting improvement; (See C.I. Program and Cards)

j) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 Customer Focus

Top management demonstrates leadership and commitment with respect to customer focus by ensuring that:

a) Customer and applicable statutory and regulatory requirements are determined, understood and consistently met; (see interested parties chart, fig 2)

b) The risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed; (see risk chart)

c) The focus on enhancing customer satisfaction is maintained. (see customer survey results)

5.2 Policy

5.2.1 Developing the Quality Policy

Top management has established, implemented and maintains a quality policy that:

a) Is appropriate to the purpose and context of the Fluid Analysis Lab and supports its strategic direction;

b) Provides a framework for setting quality objectives;

c) Includes a commitment to satisfy applicable requirements; and

d) Includes a commitment to continual improvement of the quality management system.

5.2.2 Communicating the Quality Policy

The Quality Policy:

a) is available and maintained as documented information; (see quality policy document)

b) is communicated, understood and applied within the organization; and (see Share point Site)

c) is available to relevant interested parties, as appropriate.(see Website)

Quality Policy:

<u>To enable every customer to achieve their highest level of success</u>

The strategies to accomplish this are embodied in our corporate values as follows:

- **Integrity – Our Moral character guides our actions.**
- **Commitment – We do what we say we will do.**
- **Excellence – We believe in the unlimited ability to improve.**
- **Teamwork – We harness our combined strengths as individuals.**

Anytime, anyplace, we provide accurate and timely insights making our partners reliable and efficient. The Fluid Analysis Lab is committed to

meeting applicable requirements and improving its Quality Management System.

5.3 Organizational Roles, Responsibilities, and Authorities

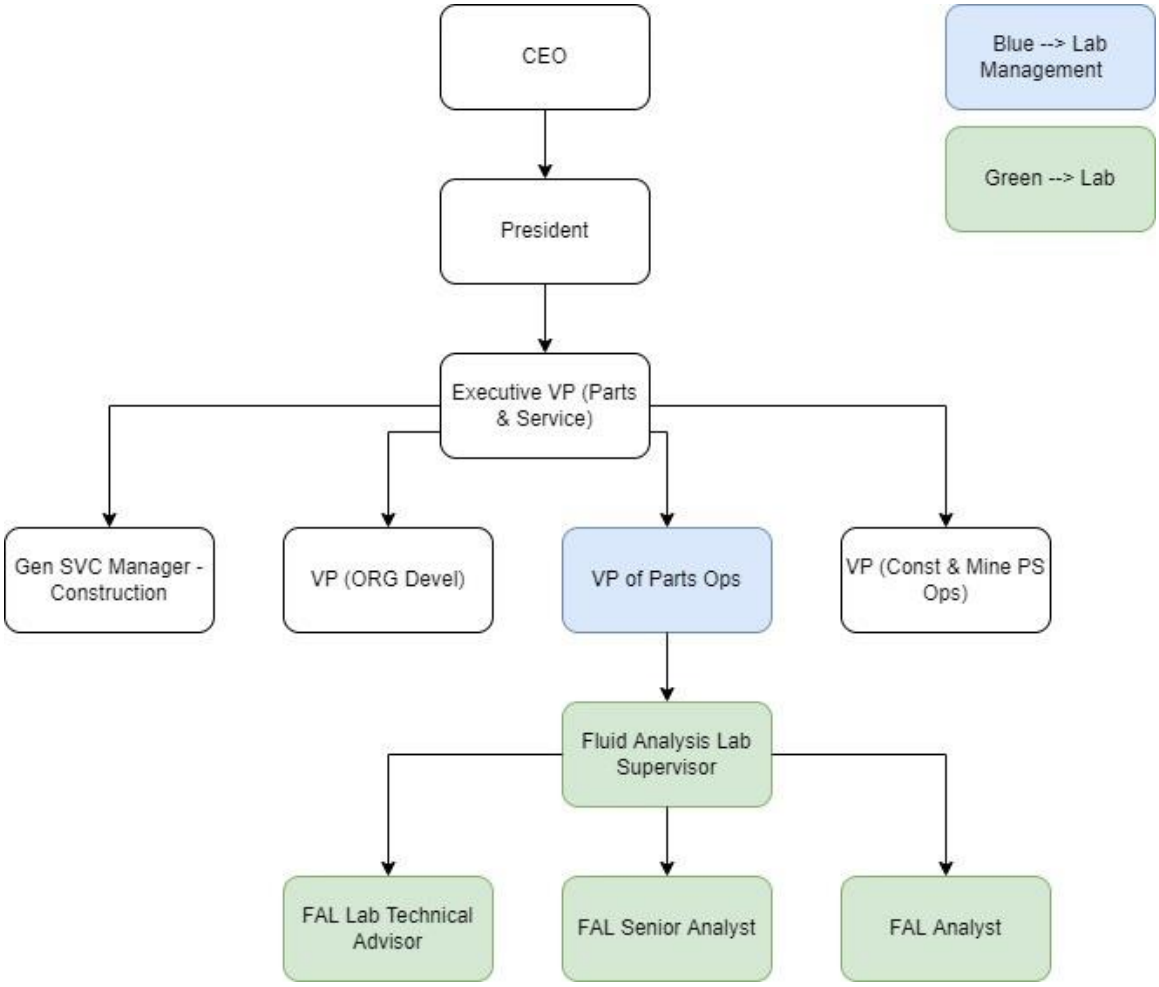

Fig 7

Top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the Fluid Analysis Lab.

Top management assigns the responsibility and authority for:

a) Ensuring that the quality management system conforms to the requirements of this International Standard; (see Management Review & internal audit procedure)

b) Ensuring that the processes are delivering their intended outputs; (see Objective Matrix & Risk chart)

c) Reporting on the performance of the quality management system and on opportunities for improvement , in particular to top management;

d) Ensuring the promotion of customer focus throughout The Fluid Analysis Lab; and

e) Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

6 Planning

6.1 Actions to Address Risks and Opportunities

6.1.1 When planning for the quality management system, The Fluid Analysis Lab considered the issues referred to in 4.1 and the requirements referred to in 4.2 and determined the risks and opportunities that need to be addressed to:

a) Give assurance that the quality management system can achieve its intended results;

b) Enhance desirable effects;

c) Prevent, or reduce, undesired effects; and

d) Achieve improvement.

6.1.2 The Fluid Analysis Lab plans:

a) Actions to address these risks and opportunities;

b) How to:

1. Integrate and implement the actions into its quality management system processes

2. Evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities are proportionate to the potential impact on the conformity of services.

6.2 Quality Objectives and Planning to Achieve Them

6.2.1 The Fluid Analysis Lab has established quality objectives at relevant functions, levels and processes needed for the quality management system.

The quality objectives are:

a) Consistent with the quality policy;

b) Measurable;

c) Taken into account applicable requirements;

d) Relevant to conformity of services and to enhancement of customer satisfaction;

e) Monitored

f) Communicated

g) Updated as appropriate.

6.2.2 When planning how to achieve its quality objectives, the Fluid Analysis Lab has determined:

a) What will be done;

b) What resources will be required;

c) Who will be responsible;

d) When it will be completed; and

e) How the results will be evaluated.

6.3 Planning of Changes

When the Fluid Analysis Lab determines the need for changes to the quality management system, the changes are carried out in a planned manner. (i.e. continuous improvement process and Standard Work Zone software)

The Fluid Analysis Lab considers:

a) The purpose of the changes and their potential consequences;

b) The integrity of the quality management system;

c) The availability of resources; and

d) The allocation or reallocation of responsibilities and authorities.

7 Support

7.1 Resources

7.1.1 General

The Fluid Analysis Lab determines and provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

The Fluid Analysis Lab considers:

a) The capabilities of, and constraints on, existing internal resources; and

b) What needs to be obtained from the external providers.

7.1.2 People

The Fluid Analysis Lab determines and provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.3 Infrastructure

The Fluid Analysis Lab determines, provides, and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services.

a) Buildings and associated utilities;

b) Equipment, including hardware and software;

c) Transportation resources; and

d) Information and communication technology.

7.1.4 Environment for the Operation of Processes

The Fluid Analysis Lab determines, provides and maintains the environment necessary for the operation of its processes and to achieve conformity services.

a) Social (e.g. non-discriminatory, calm, non-confrontational);

b) Psychological (e.g. stress reducing, burnout prevention, emotionally protective);

c) Physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

These factors can differ substantially depending on the products and services provided.

7.1.5 Monitoring and Measuring Resources

7.1.5.1 General

The Fluid Analysis Lab determines and provides the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

The Fluid Analysis Lab ensures that the resources provided:

a) Are suitable for the specific type of monitoring and measurement activities being undertaken; and

b) Are maintained to ensure their continuing fitness for their purpose.

The Fluid Analysis Lab retains appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2 Measurement Traceability

When measurement traceability is a requirement, or is considered by the Fluid Analysis Lab to be an essential part of providing confidence in the validity of measurement results, measuring equipment are:

a) Calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standard exist, the basis used for calibration or verification is retained as documented information;

b) Identified in order to determine their status; and

c) Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.
The Fluid Analysis Lab determines if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and takes appropriate action as necessary.

7.1.6 Organizational Knowledge

The Fluid Analysis Lab determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge is maintained and made available to the extent necessary.
When addressing changing needs and trends, the Fluid Analysis Lab considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates.

7.2 Competence

The Fluid Analysis Lab:

a) Determines the competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;

b) Ensures that these persons are competent on the basis of appropriate education, training, or experience;

c) Where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken; and

d) Retain appropriate documented information as evidence of competence.

7.3 Awareness

The Fluid Analysis Lab ensures that persons doing work under the The Fluid Analysis Lab's control are aware of:

a) The quality policy;

b) Relevant quality objectives;

c) Their contribution to the effectiveness of the quality management system, including the benefits of improved performance; and

d) The implication of not conforming with the quality management system requirements.

7.4 Communication

The Fluid Analysis lab determined the internal and external communications relevant to the quality management system, including:

a) On what it will communicate;

b) When to communicate;

c) With whom to communicate;

d) How to communicate; and
e) Who communicates.

7.5 Documented Information

7.5.1 General
The Fluid Analysis Lab's quality management system includes:

a) Documented information required by ISO 9001:2015; and

b) Documented information determined by the Fluid Analysis lab as being necessary for the effectiveness of the quality management system.

7.5.2 Creating and Updating

When creating an updating documented information, the Fluid Analysis Lab ensures appropriate:

a) Identification and description (e.g. title, date, author, or reference number);

b) Format (e.g. language, software version, graphics) and media (e.g. paper, electronic); and

c) Review and approval for suitability and adequacy.

7.5.3 Control of Documented Information

7.5.3.1 Documented information required by the quality management system and by ISO 9001:2015 are controlled to ensure:

a) Availability and suitable for use, where and when it is needed; and

b) It is adequately protected (e.g. from loss of confidentiality, improper use, or loss of Integrity).
7.5.3.2 For the control of documented information, the Fluid Analysis Lab has addressed the following activities, as applicable.

a) Distribution, access, retrieval and use;

b) Storage and preservation, including preservation of legibility;

c) Control of changes (e.g. version control); and

d) Retention and disposition.

Documented information of external origin determined by the Fluid Analysis Lab to be necessary for the planning and operation of the quality management system is identified as appropriate and controlled.

Documented information retained as evidence of conformity are protected from unintended alterations.

8 Operation

8.1 Operational Planning and Control

The Fluid Analysis Lab planned, implemented and controls the processes (see 4.4) needed to meet the requirements for the provision of products and services, and implemented the actions determined in Clause 6, by:

a) Determining the requirements for the products and services;

b) Establishing criteria for:
1. The processes;
2. The acceptance of products and services;

c) Determining the resources needed to achieve conformity to the product and service requirements;

d) Implementing control of the processes in accordance with the criteria; and

e) Determining and keeping documented information to the extent necessary:
1. To have confidence that the processes have been carried out as planned;
2. To demonstrate the conformity of products and services to their requirements.

The output of this planning is in a form suitable to the Fluid Analysis Lab's method of operations.

The Fluid Analysis Lab ensures that outsourced processes are controlled (See 8.4).

8.2 Requirements for Products and Services

8.2.1 Customer Communication

Communication with Customers includes:

a) Providing information relating to products and services;

b) Handling inquiries, contracts or orders, including changes;

c) Obtaining customer feedback relating to products and services, including customer complaints;

d) Handling or controlling customer property; and

e) Establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the Requirements Related to Products and Services

When determining the requirements for the product and services to be offered to customers, the Fluid Analysis Lab ensures that:

a) The requirements for the product and services are defined, including:

1) Any applicable statutory and regulatory requirements;

2) Those considered necessary by the Fluid Analysis Lab;

b) The Fluid Analysis Lab can meet the claims for the product and services it offers.

8.2.3 Review of Requirements Related to Products and Services

8.2.3.1 The Fluid Analysis Lab ensures that it has the ability to meet the requirements for products and services offered to customers. The Fluid Analysis Lab conducts a review before committing to supply products and services to a customer, to include:

a) Requirements specified by customer, including the requirements for delivery and post delivery activities;

b) Requirements not stated by the customer, but necessary for the specified intended use, when known;

c) Requirements specified by the Fluid Analysis Lab;

d) Statutory and regulatory requirements applicable to the products and services; and

e) Contract or order requirements differing from those previously expressed.

The Fluid Analysis Lab ensures that the contract or order requirements differing from those previously defined are resolved.

The customer's requirements are confirmed by the Fluid Analysis Lab before acceptance, when the customer does not provide a documented statement of their requirements.

8.2.3.2 The Fluid Analysis Lab retains documented information, as applicable:

a) On the results of the review; and

b) On any new requirements for the products and services;

8.2.4 Changes to Requirements for Products and Services

The Fluid Analysis Lab ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8.4 Control of Externally Provided Processes, Products, and Services

8.4.1 General

The Fluid Analysis Lab ensures that externally provided processes, products, and services conform to requirements.

The Fluid Analysis Lab determines the control applied to externally provided processes, products, and services when:

a) Products and services from external providers are intended for incorporation into the Fluid Analysis Lab's own products and services;

b) Products and services are provided directly to the customer(s) by external providers on behalf of the Fluid Analysis Lab; and

c) A process, or part of a process, is provided by an external provider as a result of a decision by the Fluid Analysis Lab.

The Fluid Analysis Lab determines and applies criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The Fluid Analysis Lab retains documented information of these activities and any necessary actions arising from the evaluations.

8.4.2 Type of Extent Control

The Fluid Analysis Lab ensures that externally provided processes, products and services do not adversely affect the Fluid Analysis Lab's ability to consistently deliver conforming products and services to its customers.

The Fluid Analysis Lab:

a) Ensures that externally provided processes remain within the control of its quality management system;

b) Defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;

c) Takes into consideration:

1. The potential impact of the externally provided processes, products and services on The Fluid Analysis Lab's ability to consistently meet customer and applicable statutory and regulatory requirements;

2. The effectiveness of the controls applied by the external provider;

d) Determines the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.3 Information for External Providers

The Fluid Analysis Lab ensures the adequacy of requirements prior to their communication to the external provider.

The Fluid Analysis Lab communicates to external providers its requirements for:

a) The processes, products and services to be provided;

b) The approval of:
1. Products and services;
2. Methods, processes and equipment;
3. The release of products and services;

c) Competence, including any required qualification of persons;

d) The external providers' interactions with The Fluid Analysis Lab;

e) Control and monitoring of the external providers' performance to be applied by the Fluid Analysis Lab; and

f) Verification or validation activities that the Fluid Analysis Lab, or its customer, intends to perform at the external providers' premises.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

The Fluid Analysis Lab implements production and service provision under controlled conditions.

Controlled conditions include, as applicable:

a) The availability of documented information that defines:

1. The characteristics of the products to be produced, the services to be provided, or the activities to be performed;

2. The results to be achieved;

b) The availability and use of suitable monitoring and measuring resources;

c) The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services have been met;

d) The use of suitable infrastructure and environment for the operation of processes;

e) The appointment of competent persons, including any required qualification;

f) The validation and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

g) The implementation of actions to prevent human error; and

h) The implementation of release, delivery and post-delivery activities.

8.5.2 Identification and Traceability

The Fluid Analysis Lab uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

The Fluid Analysis Lab identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

The Fluid Analysis Lab controls the unique identification of the outputs when traceability is a requirement and retains the documented information necessary to enable traceability.

8.5.3 Property Belonging to Customers or External Providers

The Fluid Analysis Lab exercises care with property belonging to customer or external providers while it is under the Fluid Analysis Lab's control or being used by the Fluid Analysis Lab.

The Fluid Analysis Lab identifies, verifies, protects and safeguards customer's or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the Fluid Analysis Lab reports this to the customer or external provider and retains documented information on what has occurred.

8.5.4 Preservation

The Fluid Analysis Lab preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

8.5.5 Post-delivery Activities

The Fluid Analysis Lab meets requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, the Fluid Analysis Lab considers:

a) Statutory and regulatory requirements;

b) The potential undesired consequences associated with its products and services;

c) The nature, use and intended lifetime of its products and services;

d) Customer requirements; and

e) Customer Feedback.

8.5.6 Control of Changes

The Fluid Analysis Lab reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

The Fluid Analysis Lab retains documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

8.6 Release of Products and Service

The Fluid Analysis Lab has implemented planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

The release of products and services to the customer, do not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

The Fluid Analysis Lab retains documented information on the release of products and services. The documented information includes:

a) Evidence of conformity with the acceptance criteria;

b) Traceability to the person(s) authorizing the release.

8.7 Control of Nonconforming Outputs

8.7.1 The Fluid Analysis Lab ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

The Fluid Analysis Lab takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This also applies to nonconforming products and services detected after delivery of products, during or after the provision of services.

The Fluid Analysis Lab deals with nonconforming outputs in one or more of the following ways:

a) Correction;

b) Segregation, containment, return or suspension of provision of products and services;

c) Informing the customer; and

d) Obtaining authorization for acceptance under concession.

Conformity to the requirements are verified when nonconforming outputs are corrected.

8.7.2 The Fluid Analysis Lab retains documented information that:

a) Describes the nonconformity;

b) Describes the actions taken;

c) Describes any concessions obtained; and

d) Identifies the authority deciding the action in respect of the nonconformity.

9 Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

The Fluid Analysis Lab determines:

a) What needs to be monitored and measured;

b) The methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;

c) When the monitoring and measuring is performed;

d) When the results form monitoring and measurement are analyzed and evaluated.

The Fluid Analysis Lab evaluates the performance and the effectiveness of the quality management system.

The Fluid Analysis Lab retains appropriate documented information as evidence of the results.

9.1.2 Customer Satisfaction

The Fluid Analysis Lab monitors customers' perceptions of the degree to which their needs and expectation have been fulfilled. The Fluid Analysis Lab determines the methods for obtaining, monitoring and reviewing this information.

9.1.3 Analysis and Evaluation

The Fluid Analysis Lab analyzes and evaluates appropriate data and information arising from monitoring and measurement.

The results of analysis are used to evaluate:

a) Conformity of products and services;

b) The degree of customer satisfaction;

c) The performance and effectiveness of the quality management system;

d) If planning has been implemented effectively;

e) The effectiveness of actions taken to address risks and opportunities;

f) The performance of external providers; and

g) The need for improvements to the quality management system.

9.2 Internal Audit

9.2.1 The Fluid Analysis Lab conducts internal audits at planned intervals to provide information on whether the quality management system:

a) Conforms to:

1. The Fluid Analysis Lab's own requirements for its quality management system;

2. The requirements of ISO 9001:2015

b) Is effectively implemented and maintained.

9.2.2 The Fluid Analysis Lab has:

a) Planned, established, implemented and maintains an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which is taken into consideration the importance of the processes concerned, changes affecting the Fluid Analysis Lab, and the results of previous audits;

b) Defined the audit criteria and scope of each audit;

c) Selected auditors and conducts audits to ensure objectively and the impartiality of the audit process;

d) Ensured that the results of the audits are reported to relevant management;

e) Take appropriate correction and corrective actions without undue delay; and

f) Retain documented information as evidence of the implementation of the audit program and the audit results.

9.3 Management Review

9.3.1 General

Top management reviews the Fluid Analysis Lab's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the Fluid Analysis Lab.

9.3.2 Management Review Inputs

Management review is planned and carried out taking into consideration:

a) The status of actions from previous management reviews;

b) Changes in external and internal issues that are relevant to the quality management system;

c) Information on the performance and effectiveness of the quality management system, including trends in:

1. Customer satisfaction and feedback from relevant interested parties;

2. The extent to which quality objectives have been met;
3. Process performance and conformity of products and services;

4. Nonconformities and corrective actions;

5. Monitoring and measurement results;

6. Audit results;

7. The performance of external providers;

d) The adequacy of resources;

e) The effectiveness of actions taken to address risks and opportunities (see 6.1); and

f) Opportunities for improvement

9.3.3 Management Review Outputs

The outputs of the management review include decisions and actions related to:

a) Opportunities for improvement;

b) Any need for changes to the quality management system; and

c) Resource needs.

The Fluid Analysis Lab retains documented information as evidence of the results of management reviews.

10 Improvement

10.1 General

The Fluid Analysis Lab determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction.

These include:

a) Improving products and services to meet requirements as well as to address future needs and expectations;

b) Correcting, preventing or reducing undesired effects; and

c) Improving the performance and effectiveness of the quality management system.

10.2 Nonconformity and Corrective Action

10.2.1 When nonconformity occurs, including any arising from complaints,

The Fluid Analysis Lab:

a) Reacts to the nonconformity and, as applicable:

1. Takes action to control and correct it;

2. Deals with the consequences;

b) Evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

1. Reviewing and analyzing the nonconformity;

2. Determining the causes of the nonconformity;

3. Determining if similar nonconformities exist, or could potentially occur;

c) Implements any action needed;

d) Reviews the effectiveness of any corrective action taken;

e) Updates risks and opportunities determined during planning, if necessary; and

f) Makes changes to the quality management system, if necessary.

Corrective actions are appropriate to the effects of the nonconformities encountered.

10.2.2 The Fluid Analysis Lab retains documented information as evidence of:

a) The nature of the nonconformities and any subsequent actions taken; and

b) The results of any corrective action.

10.3 Continual Improvement

The Fluid Analysis Lab continually improves the suitability, adequacy and effectiveness of the quality management system.

The Fluid Analysis Lab considers the results of analysis and evaluations, and the outputs from the management review, to determine if there are needs or opportunities that are addressed as part of the continual improvement.