QMS MANUAL

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QHSE PROCEDURE

Viking Industrial

Approval and revision status

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Areas affected by recent revision are recorded in the above table

TABLE OF CONTENTS

1.0 SCOPE

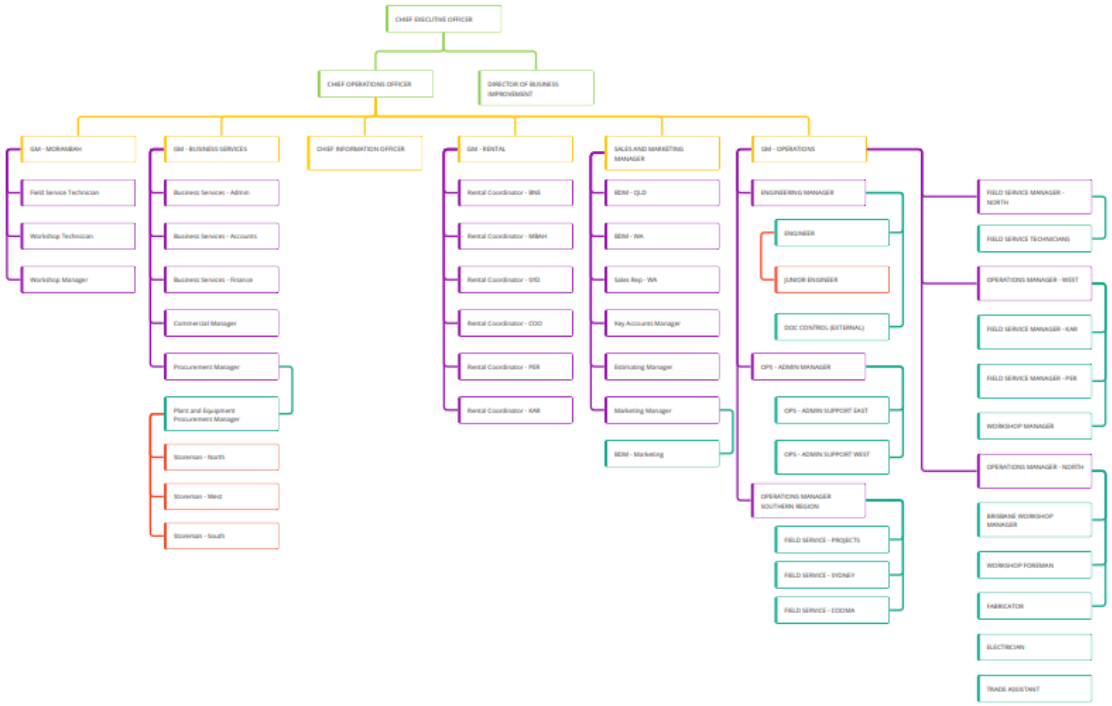
This Quality Manual contains policies that have been implemented at **VIKING INDUSTRIAL PTY LTD.**
This manual pertains to processes relating to:
The manual and related quality system documentation are written to comply with the requirements of ISO 9001

2.0 COMPANY CONTEXT

As a proudly Australian company, VIKING INDUSTRIAL trading since 2013, we're experts in fixed speed diesel engines and power generation, but our reach goes far beyond our shores. We've got access to a world-wide supply chain of engine and parts suppliers, ensuring we deliver top-notch quality and value to our clients, no matter the project. Our departments collaborate seamlessly, ensuring your project stays on target without distraction. No matter the challenge, Viking Industrial is prepared for the task.

VIKING INDUSTRIAL is one of Australia's largest privately owned equipment providers with dedicated branches in Brisbane, Gold Coast, Sydney, Cooma, Perth, Karratha, and Mackay. Our current expansion plan involves new branches in Melbourne and Darwin. We also offer a comprehensive dealer network Australia wide through our partnerships with Scania and Volvo Penta.

At VIKING INDUSTRIAL our dedicated team of professionals is drawn from diverse backgrounds, unified by their commitment to hard work and precision. Our sales, rental and service divisions are supported further by our expertise in project management, engineering and Australian mine spec requirements. VIKING INDUSTRIAL has proudly supplied equipment for sale and hire to many of Australia's largest Mining, Industrial, Construction, Rental and Government organisations.



3.0 TERMS AND DEFINITIONS

Throughout this Quality Manual, the term “organisation” refers to **VIKING INDUSTRIAL PTY LTD**
Quality Management System (QMS) refers to a system that considers the three mains components: quality control, quality assurance and quality improvement.
Quality management is focused not only on product or service quality, but also the means to achieve it. A QMS, therefore, uses quality assurance and control of processes, as well as products/services to achieve more consistent quality.

4.0 QMS

4.1 GENERAL REQUIREMENTS

The organisation **VIKING INDUSTRIAL PTY LTD** has established, documented, implemented, and currently maintains a QMS. We continually improve its effectiveness in accordance with the requirements of ISO 9001.

The organisation:

- has determined the processes needed for the QMS and their application throughout the organisation ,
- determined the sequence and interaction of these processes,
- determined criteria and methods needed to ensure that both the operation and control of these processes are effective,
- ensures the availability of resources and information necessary to support the operation and monitoring of these processes,
- monitors, measures where applicable, and analyses these processes, and o implements actions necessary to achieve planned results and continual improvement of these processes.

4.2 DOCUMENTATION REQUIREMENTS

4.2.1 GENERAL

The QMS documentation includes:

- Documented statements of a quality policy and quality objectives,
- a quality manual,
- documented procedures and records required by ISO 9001, including
- Document Control, Record Control, Internal Audit, Control of Non-conforming Product, Corrective and Preventive Action,
- documents, including records, determined by the organisation to be necessary to ensure the effective planning, operation and control of its processes.

4.2.2 QUALITY MANUAL

The organisation has established and currently maintains a quality manual that includes:

- the scope of the QMS, including details of and justification for any exclusions,
- the documented procedures established for the QMS, or
- reference to them, and
- a description of the interaction between the processes of the QMS

The Quality Department is responsible for maintaining the quality manual.

4.2.3 DOCUMENT CONTROL

Documents required by the QMS are controlled. Records are a special type of document and are controlled according to the requirements given in section 4.2.4.

- A documented procedure has been established (see Control of Documents Procedure) to define the controls needed: to approve documents for adequacy prior to issue,
- to review and update as necessary and re-approve documents,
- to ensure that changes and the current revision status of documents are identified,
- to ensure that relevant versions of applicable documents are available at points of use,
- to ensure that documents remain legible and readily identifiable,
- to ensure that documents of external origin determined by the organisation to be necessary for the planning and operation of the QMS are identified and their distribution controlled, and
- to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

The Document Control Manager is responsible to maintain the Document Control Procedure, to ensure that relevant versions are available at points of use, to remove obsolete documents, and to control external documents. Documents are reviewed and approved, including re-approval as required, by the appropriate functional manager along with the Quality Manager

4.2.4 CONTROL OF RECORDS

Records established to provide evidence of conformity to requirements and of the effective operation of the QMS shall be controlled.

A documented procedure has been established (Document Control Procedure) to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Records are legible, readily identifiable and retrievable.

The Document Control Manager is responsible to maintain the Records Control Procedure.

5.0 MANAGEMENT RESPONSIBILITY

5.1 MANAGEMENT COMMITMENT

Top management provides evidence of its commitment to the development and implementation of the QMS and continually improve its effectiveness by:

- communicating to the organisation the importance of meeting customer as well as
- statutory and regulatory requirements,
- establishing the quality policy,
- ensuring that quality objectives are established,
- conducting management reviews, and
- ensuring the availability of resources.

Top management is considered to be the Quality Steering Team.

5.2 CUSTOMER FOCUS

Top management ensures that customer requirements are determined and are met with the aim of enhancing customer satisfaction.

5.3 QUALITY POLICY

Top management ensures that the quality policy:

- is appropriate to the purpose of the organisation,
- includes a commitment to comply with requirements and continually improve the effectiveness of the QMS,
- provides a framework for establishing and reviewing quality objectives,
- is communicated and understood within the organisation, and
- is reviewed for continuing suitability.

The stated quality policy is as follows:

It is the policy of the Company to operate its business in a manner that consistently meets or exceeds the quality standards set by affected stakeholders – being customers, industry regulators and the communities within which Company operations are conducted. The Company is committed to continuously improving the quality of Company operations and the services provided by the company.

Service quality is a customer determination and as such the Company will strive to:

- Complying with statutory obligations, standards, specifications and codes of practice relevant to quality management

- Maintaining, monitoring, reviewing, auditing and continually improving our systems and methods to work towards becoming compliant with certification requirements of ISO 9001
- Engaging suitably qualified, skilled, and experienced people
- Educating and training in order to continually improve the skills of our people, awareness and knowledge of quality issues and practices
- Identifying, reporting, investigating, and resolving all non-conformances and taking action to prevent recurrence
- Establishing, reviewing, and communicating performance measures and taking action to improve outcomes
- Monitoring and evaluating the quality performance of consultants, subcontractors and suppliers and implementing effective communication with them on quality and compliance issues.

The Company supports the adoption of appropriate quality systems (for example ISO 9001, ISO 14001 & ISO 45001) in order that all stakeholders benefit from this quality commitment.

The Quality Manager is responsible for ensuring the quality policy is reviewed during the Management Review process.

5.4 PLANNING

5.4.1 QUALITY OBJECTIVES

Top management ensures that quality objectives, including those needed to meet requirements for product and services, are established at relevant functions and levels within the organisation. The quality objectives are measurable and consistent with the quality policy.

5.4.2 QMS PLANNING

Top management ensures that:

the planning of the QMS is carried out in order to meet the requirements given in section 4.1, as well as the quality objectives, and the integrity of the QMS is maintained when changes to the QMS are planned and implemented.

5.5 RESPONSIBILITY, AUTHORITY AND COMMUNICATION

5.5.1 RESPONSIBILITY AND AUTHORITY

Top management ensures that responsibilities and authorities are defined and communicated within the organisation.

5.5.2 MANAGEMENT REPRESENTATIVE

Top management has appointed a member of management who, irrespective of other responsibilities, has responsibility and authority that includes:

- ensuring that processes needed for the QMS are established, implemented and maintained,
- reporting to Top management on the performance of the QMS and any need for improvement, and
- ensuring the promotion of awareness of customer requirements throughout the organisation.

The appointed management representative is the **PROJECT MANAGER** They serve as the liaison to external parties on matters relating to the QMS.

5.5.3 INTERNAL COMMUNICATION

Top management ensures that appropriate communication processes are established within the organisation and that communication takes place regarding the effectiveness of the QMS.

5.6 MANAGEMENT REVIEW

Top management reviews the organisation 's QMS, at planned intervals (at least annually), to ensure its continuing suitability, adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives.

Records from management reviews are maintained by the Quality Manager

The input to management review includes information on:

- results of audits,
- customer feedback,
- process performance and product conformity,
- status of preventive and corrective actions,
- follow-up actions from previous management reviews,
- changes that could affect the QMS, and
- recommendations for improvement.

The output from the management review includes:

- any decisions and actions related to improvement of the effectiveness of the QMS and its processes,
- improvement of products and services related to customer requirements, and
- resource needs.

6.0 RESOURCES MANAGEMENT

6.1 PROVISION OF RESOURCES

The organisation determines and provides the resources needed to implement and maintain the QMS and continually improve its effectiveness and to enhance customer satisfaction by meeting customer requirements. Resource needs are discussed during management review.

6.2 HUMAN RESOURCES

6.2.1 GENERAL

Personnel performing work affecting conformity to product requirements are deemed competent on the basis of appropriate education, training, skills and experience. The Human Resources Department is responsible for assessing competence.

6.2.2 COMPETENCE, TRAINING AND AWARENESS

The organisation:

- determines the necessary competence for personnel performing work affecting conformity to product and service requirements,
- where applicable, provides training or takes other actions to achieve the necessary competence,
- evaluates the effectiveness of the actions taken,
- ensures that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and maintains appropriate records of education, training, skills and experience.

The Human Resources Department is responsible to determine competency requirements and to oversee the training process.

Human Resources also maintains appropriate records of education, training, skills, and experience.

As of the initial release of this document, all current employees are competent.

6.3 INFRASTRUCTURE

The organisation determines, provides, and maintains the infrastructure needed to achieve conformity to product requirements.

Infrastructure includes, as applicable:

- buildings, workspace and associated utilities,
- process equipment (both hardware and software), and
- supporting services (such as transport, communication or information systems).

6.4 WORK ENVIRONMENT

The organisation determines and manages the work environment needed to achieve conformity to product and services requirements. The Facilities Department is responsible to identify and control work environment requirements

7.0 PRODUCT REALISATION

7.1 PLANNING OF PRODUCT REALISATION

The organisation plans and develops the processes needed for product realisation.

Planning of product realisation is consistent with the requirements of the other processes of the QMS.

In planning product realisation, the organisation determines the following, as appropriate:

- quality objectives and requirements for the product,
- the need to establish processes and documents, and to provide resources specific to the product,
- required verification, validation, monitoring, measurement, inspection and test activities, specific to the product and the criteria for product acceptance,
- records needed to provide evidence that the realisation processes and resulting product meet requirements.

The output of this planning is in a form suitable for the organisation's method of operations.

The Planning Department is responsible for planning production or service provision and for maintaining associated records.

7.2 CUSTOMER-RELATED PROCESSES

7.2.1 DETERMINATION OF REQUIREMENTS RELATED TO THE PRODUCT

The organisation determines:

- requirements specified by the customer, including the requirements for delivery and postdelivery activities,
- requirements not stated by the customer but necessary for specified or intended use, where known,
- statutory and regulatory requirements applicable to the product, and
- any additional requirements considered necessary by the organisation.

The Sales Department is responsible for determining all customer requirements, whether specified; not stated, but necessary; or statutory and regulatory.

7.2.2 REVIEW OF REQUIREMENTS RELATED TO THE PRODUCT

The organisation reviews the requirements related to the product. This review is conducted prior to the organisation's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and ensures that:

- product requirements are defined.
- contract or order requirements differing from those previously expressed are resolved, and
- the organisation has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review are maintained. The Sales Department is responsible for the review and for maintaining the records.

Where the customer provides no documented statement of requirement, the customer requirements are confirmed by the organisation before acceptance.

Where product requirements are changed, the Sales Department ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 CUSTOMER COMMUNICATION

The organisation determines and implements effective arrangements for communicating with customers in relation to:

- product information,
- enquiries, contracts or order handling, including amendments, and
- customer feedback, including customer complaints.

Product information is maintained by the sales department.

Customer enquiries, contracts, orders, etc. are received by the sales department. Customer feedback is recorded and managed by the sales department.

7.3 DESIGN AND DEVELOPMENT

7.3.1 DESIGN AND DEVELOPMENT PLANNING

The organisation plans and controls the design and development of product. The Engineering Department is responsible for controlling all stages of the design process, and for maintaining the appropriate records.

During the design and development planning, the organisation determines:

- the design and development stages,

- the review, verification and validation that are appropriate to each design and development stage, and
- the responsibilities and authorities for design and development.

The organisation manages the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output is updated, as appropriate, as the design and development progresses.

7.3.2 DESIGN AND DEVELOPMENT INPUTS

Inputs relating to product requirements are determined and records maintained. These inputs include:

- functional and performance requirements,
- applicable statutory and regulatory requirements,
- where applicable, information derived from previous similar designs, and
- other requirements essential for design and development.

The inputs are reviewed for adequacy. Requirements are complete, unambiguous and not in conflict with each other.

7.3.3 DESIGN AND DEVELOPMENT OUTPUTS

The outputs of design and development are in a form suitable for verification against the design and development input and are approved prior to release.

Design and development outputs:

- meet the input requirements for design and development,
- provide appropriate information for purchasing, production and service provision,
- contain or reference product acceptance criteria, and
- specify the characteristics of the product that are essential for its safe and proper use.

7.3.4 DESIGN AND DEVELOPMENT REVIEW

At suitable stages, systematic reviews of design and development are performed in accordance with planned arrangements:

- to evaluate the ability of the results of design and development to meet requirements, and
- to identify any problems and propose necessary actions.

Participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions are be maintained.

7.3.5 DESIGN AND DEVELOPMENT VERIFICATION

Verification is performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions are maintained.

7.3.6 DESIGN AND DEVELOPMENT VALIDATION

Design and development validation is performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation is completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions are maintained.

7.3.7 DESIGN AND DEVELOPMENT CHANGES

Design and development changes are identified, and records maintained. The changes are reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes includes evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions are be maintained.

7.4 PURCHASING

7.4.1 PURCHASING PROCESS

The organisation ensures that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organisation evaluates and selects suppliers based on their ability to supply product in accordance with the organisation 's requirements. Criteria for selection, evaluation and re-evaluation are established.

Records of the results of evaluations and any necessary actions arising from the evaluation are maintained **in management review**.

The Purchasing Department is responsible for controlling the purchasing process and for maintaining appropriate records.

As of the initial release of this document, all current suppliers in good standing are considered to be approved.

7.4.2 PURCHASING INFORMATION

Purchasing information describes the product and or service to be purchased, including where appropriate:

- requirements for approval of product, procedures, processes and equipment,
- requirements for qualification of personnel, and
- QMS requirements.

The organisation ensures the adequacy of specified purchase requirements prior to communication to the supplier.

7.4.3 VERIFICATION OF PURCHASED PRODUCT

The organisation establishes and implements the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organisation or its customer intends to perform verification at the supplier's premises, the organisation states the intended verification arrangements and method of product release in the purchasing information.

7.5 PRODUCTION AND SERVICE PROVISION

7.5.1 CONTROL OF PRODUCTION AND SERVICE PROVISION

The organisation plans and carries out production and service provision under controlled conditions. Controlled conditions include, as applicable:

- the availability of information that describes the characteristics of the product,
- the availability of work instructions, as necessary,
- the use of suitable equipment,
- the availability and use of monitoring and measuring equipment,
- the implementation of monitoring and measurement, and
- the implementation of product release, delivery and post-delivery activities.

The Production Department is responsible for controlling all phases or product and service provision and for maintaining appropriate records.

7.5.2 VALIDATION OF PROCESSES FOR PRODUCTION AND SERVICE PROVISION

The organisation validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, consequently, deficiencies become apparent only after the product is in use or the service has been delivered.

Validation demonstrates the ability of these processes to achieve planned results.

The organisation establishes arrangements for these processes including, as applicable:

- defined criteria for review and approval of the processes,
- approval of equipment and qualification of personnel,
- use of specific methods and procedures,
- requirements for records, and
- revalidation.

7.5.3 IDENTIFICATION AND TRACEABILITY

Where appropriate, the organisation identifies the product by suitable means throughout product realisation. The organisation identifies the product status with respect to monitoring and measurement requirements throughout product realization.

Where traceability is a requirement, the Production Department controls the unique identification of the product and maintains records.

7.5.4 CUSTOMER PROPERTY

The organisation exercises care with customer property while it is under the organisation 's control or being used by the organisation . The organisation identifies, verifies, protects and safeguards customer property provided for use or incorporation into the product.

If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organisation shall report this to the customer and maintain records. Customer property can include intellectual property and personal data.

Customer property includes equipment, components, drawings and other customer documentation.

The Production Department is responsible for controlling and recording customer property.

The Sales Department is responsible for all communication with the customer regarding their property.

7.5.5 PRESERVATION OF PRODUCT

The Production Department is responsible for preserving the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, this preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

7.6 CONTROL OF MONITORING AND MEASURING EQUIPMENT

The organisation determines the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. The organisation establishes processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

The Quality Department is responsible for all aspects related to the system of controlling monitoring and measurement.

Where necessary to ensure valid results, measuring equipment is:

- calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification is recorded,
- adjusted or re-adjusted as necessary,
- identified to determine its calibration status,
- safeguarded from adjustments that would invalidate the measurement result,
- protected from damage and deterioration during handling, maintenance, and storage.

In addition, the organisation assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. The organisation takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are be maintained.

8.0 MEASUREMENT, ANALYSIS, AND IMPROVEMENT

8.1 GENERAL

The organisation plans and implements the monitoring, measurement, analysis and improvement processes needed:

- to demonstrate conformity to product requirements,
- to ensure conformity of the QMS, and
- to continually improve the effectiveness of the QMS.

This includes determination of applicable methods, including statistical techniques, and the extent of their use. The Quality Department is responsible for systems related to monitoring, measurement, analysis and improvement.

8.2 MONITORING AND MEASUREMENT

8.2.1 CUSTOMER SATISFACTION

As one of the measurements of the performance of the QMS, the organisation monitors information relating to customer perception as to whether the organisation has met customer requirements.

The methods for obtaining and using this information are determined by the Sales Department

8.2.2 INTERNAL AUDIT

The organisation conducts internal audits at planned intervals to determine whether the QMS:

- conforms to the planned arrangements, to the requirements of ISO 9001 and to the QMS requirements established by the organisation , and
- is effectively implemented and maintained.

An audit program has been planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined. This selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process. Auditors do not audit their own work.

A documented procedure has been established (see Internal Audit Procedure) to define the responsibilities and requirements for planning and conducting audits, establishing records and for reporting results.

Records of the audits and their results are maintained. The Quality Department is responsible to oversee the internal auditing system and for maintaining appropriate records.

The management responsible for the area being audited ensures that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

8.2.3 MONITORING AND MEASUREMENT OF PROCESSES

The organisation applies suitable methods for monitoring and, where applicable, measurement of the QMS processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken by the appropriate personnel, to ensure conformity of the product.

8.2.4 MONITORING AND MEASUREMENT OF PRODUCT

The organisation monitors and measures the characteristics of the product to verify that product requirements have been met. This is carried out at appropriate stages of the product realisation process in accordance with the planned arrangements.

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person(s) authorising release of product for delivery to the customer.

The release of product and delivery of service to the customer does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.3 CONTROL OF NONCONFORMING PRODUCT

The organisation ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure has been established (see Control of Nonconforming Product Procedure) to define the controls and related responsibilities and authorities for dealing with nonconforming product.

Where applicable, the organisation deals with nonconforming product by one or more of the following ways:

- by taking action to eliminate the detected nonconformity.
- by authorising its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
- by taking action to preclude its original intended use or application;
- by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

When nonconforming product is corrected, it is subject to re-verification to demonstrate conformity to the requirements.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained.

8.4 ANALYSIS OF DATA

The organisation determines, collects and analyses appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to:

- customer satisfaction,
- conformity to product requirements,
- characteristics and trends of processes and products including opportunities for preventive action, and
- suppliers.

The Quality Department is responsible for determining the data requirements and for coordinating with other departments to collect and subsequently analyse the data in order to make improvements.

8.5 IMPROVEMENT

8.5.1 CONTINUAL IMPROVEMENT

The organisation continually improves the effectiveness of the QMS using the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and results of the management review meetings.

8.5.2 CORRECTIVE ACTION

The organisation takes action to eliminate the cause of nonconformities in order to prevent their recurrence.

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

A documented procedure has been established that defines requirements for:

- reviewing nonconformities (including customer complaints),
- determining the causes of nonconformities,
- evaluating the need for action to ensure that nonconformities do not recur,
- determining and implementing action needed,
- recording and maintaining records of the results of action taken, and
- reviewing the effectiveness of the corrective action taken.

The Quality Department is responsible for maintaining the procedure and the associated records.

8.5.3 PREVENTIVE ACTION

The organisation determines action to eliminate the causes of potential nonconformities to prevent their occurrence.

Preventive actions are appropriate to the effects of the potential problems

A documented procedure has been established (see Corrective and Preventive Action Procedure) to define requirements for

- determining potential nonconformities and their causes,
- evaluating the need for action to prevent occurrence of nonconformities,
- determining and implementing action needed,
- recording and maintaining the results of action taken, and
- reviewing the effectiveness of the preventive action taken.

The Quality Department is responsible for maintaining the procedure and the associated records.