



www.cynergiconsultants.com

Quality Management System Manual

ISO 9001:2000

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

Table of Contents

Table of Contents	2
1. General	5
1.1 Purpose and scope.....	5
1.2 Application.....	5
1.3 Applicable standards and regulations.....	5
2 Company Information	6
3 Definitions and Conventions	6
4 Quality Management System	8
4.1 General requirements.....	8
Figure 1 Model of a Process-Based QMS.....	9
4.2 Documentation requirements.....	10
4.2.1 General.....	10
4.2.2 QMS manual.....	10
4.2.3 Management of documents.....	11
4.2.4 Management of records.....	11
5 Management Responsibility	11
5.1 Management commitment.....	11
5.2 Customer focus.....	12
5.3 Quality policy.....	12
5.4. Planning.....	13
5.4.1 Quality objectives.....	13
5.4.2 QMS planning.....	13
5.5 Responsibility, authority and communication.....	13
5.5.1 Responsibility and authority.....	13
5.5.2 Management representative.....	13
5.5.3 Internal communication.....	14
5.6 Management review.....	14
5.6.1 General.....	14
5.6.2 Review Input.....	14
5.6.3 Review output.....	15
6 Resource Management	15
6.1 Provision of resources.....	15
6.2 Human resources.....	15

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

6.2.1	General.....	15
6.2.2	Competence, awareness and training	16
6.3	Infrastructure	16
6.4	Work environment.....	16
7	Product Realisation	17
7.1	Planning of product realisation	17
7.2	Customer-related processes.....	17
7.2.1	Determination of requirements related to the product.....	17
7.2.2	Review of requirements related to the product	17
7.2.3	Customer communication	18
7.3	Design and development - exclusion	19
7.4	Purchasing - exclusion.....	19
7.5	Production and service	19
7.5.1	Management of production and service - exclusion.....	19
7.5.2	Validation of processes for production and service - exclusion.....	19
7.5.3	Identification and traceability - exclusion	19
7.5.4	Customer property.....	19
7.5.5	Preservation of product - exclusion	20
7.6	Management of measuring and monitoring devices	20
8	Measurement, Analysis and Improvement.....	21
8.1	General.....	21
8.2	Monitoring and measurement.....	21
8.2.1	Customer satisfaction	21
8.2.2	Internal audits.....	21
8.2.3	Monitoring and measurement of processes.....	22
8.2.4	Monitoring and measurement of product	22
8.3	Management of non-conforming product	23
8.4	Analysis of data	24
8.5	Improvement.....	24
8.5.1	Continual improvement.....	24
8.5.2	Corrective action.....	25
8.5.3	Preventive action	25
Appendix A - Quality Policy Display.....		26
Appendix B - BPI Matrix		28
Appendix C - Document Master List.....		29
Appendix D - Records Procedure		30
Appendix E - Process Interaction Matrix		32
Appendix F - Subcontractor Selection Procedure		33
Appendix G - Training Procedure		35
Appendix H - Document Management Procedure		37

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

Appendix J - Document Master List	38
Appendix K - Communications Procedure	39
Appendix L - Management Review Procedure	40
Appendix M - Resource Management Procedure.....	43
Appendix N - Organisation Chart.....	44
Appendix P - Infrastructure Procedure	45
Appendix Q - Service Delivery Procedure	46
Appendix Q - Service Delivery Procedure	46
Appendix R - Marketing Procedure	49
Appendix S - Post Marketing Surveillance Procedure.....	50
Appendix T - NC - CAPA Procedure	51
Appendix V - Audit Procedure	53

1. General

1.1 Purpose and scope

This manual documents the Quality Management System (QMS) of Cynergin Consultants Ltd. to demonstrate the ability of the company to consistently provide products and services that meet customer and regulatory requirements. This manual establishes compliance with those standards and regulations listed in the [Applicable standards and regulations](#) (Ref. Para. 1.3). This manual applies to project management, consulting, sales, marketing, outsourced design, installation and servicing activities conducted or supervised by Cynergin Consultants Ltd, as the case may be.

This manual follows the format of ISO 9001:2000 standard and establishes a reference structure for the second level documentation.

1.2 Application

Where any requirements of [Applicable standards and regulations](#), cannot be applied to the QMS due to the nature of Cynergin Consultants Ltd's activities and its products and are permissible exclusions from the QMS, they are identified as exclusions with justification in the applicable sections of this QMS manual.

1.3 Applicable standards and regulations

- [ISO 9001:2000, Quality Management System - Requirements](#)
- [ISO 9000:2005, Quality Management System – Fundamentals and Vocabulary](#)
- [ISO 19011, Guidelines for Quality and/or Environmental Management Systems Auditing](#)
- [The Management of Health & Safety at Work Regulations 1999](#)

Cynergin Consultants Ltd. also considers for its deliverables, as required, the following regulations:

- [The Construction \(Design and Management\) Regulations 1994](#)
- [The Building Regulations Part L](#)
- [CIBSE Guide F - Energy Efficiency in Buildings](#)
- [Good Practice Guide 306 Energy Management Priorities for Existing Buildings](#)

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

2 Company Information

Cynergin Consultants Ltd. is located at 19 Strathmore Drive, Reading, RG10 9QT UK. Cynergin Consultants Ltd. sells and markets the following services:

- [Outsourced design, procurement and project management for energy efficiency and green energy engineering initiatives](#) including boiler replacement and conversion, Combined Heat and Power (CHP), micro CHP, absorption cooling, renewables, new technologies, control systems and energy efficient lighting.
- [Technical advice and procurement for clients \(ESCO's and/or Public Authorities\) wishing to participate in Contract Energy Management \(CEM\) or Energy Saving Performance Contracts \(ESPC\)](#). We have a deep understanding of the National Health Service, Education and Local Authority markets as witnessed by our track record of nearly twenty successful £million pound plus multi-technology CEM & ESPC projects.
- [Carbon and related emissions assessment and management](#). Production, facilitation and implementation of a carbon management programme, master plan or strategy to reduce carbon costs and migrate to a zero net carbon or carbon neutral operation through efficiency measures, investment in new technologies and supply chain management.
- [General energy management including auditing, monitoring and targeting, tariff negotiations, energy conservation and advice on the climate change levy](#). We undertake energy audits and assessments and advise on the impact of Carbon Dioxide (CO₂) emissions and the European Union Emissions Trading Scheme (ETS). We can identify customers' carbon and greenhouse gas emissions costs.

Detailed information on the organizations' services and its contact information may be found on Cynergin Consultants Ltd's. website at <http://www.cynerginconsultants.com>.

3 Definitions and Conventions

- | | |
|--------------------------|---|
| All applicable standards | - Where the term <i>all applicable standards</i> is used within this manual, all documents listed in the Applicable standards and regulations (Ref. Para. 1.3) shall apply. |
| BPI matrix | - Business performance indicator matrix. |
| NC-CAPA | - Non-conformity & Corrective and Preventive Action. |
| Management Team | - Executive Directors form the Management team. The Management team has executive responsibility for |

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

	performance of the business and quality management system.
Product	- A result of a process (ISO 9000:2005)
‘Underlined’ procedure	- Underlined procedures and standards in the body of this manual identify documents that support particular elements of this manual. Some have been included as an Appendix at the rear of this manual.
ESCO	Energy Services Company
TBI	To be included
TBD	To be defined

4 Quality Management System

4.1 General requirements

Cynergin Consultants Ltd. has established, documented, implemented, and maintains its QMS in accordance with the requirements of [all applicable standards](#) and regulations. Cynergin Consultants Ltd. continually improves the effectiveness of its QMS.

Cynergin Consultants Ltd. QMS:

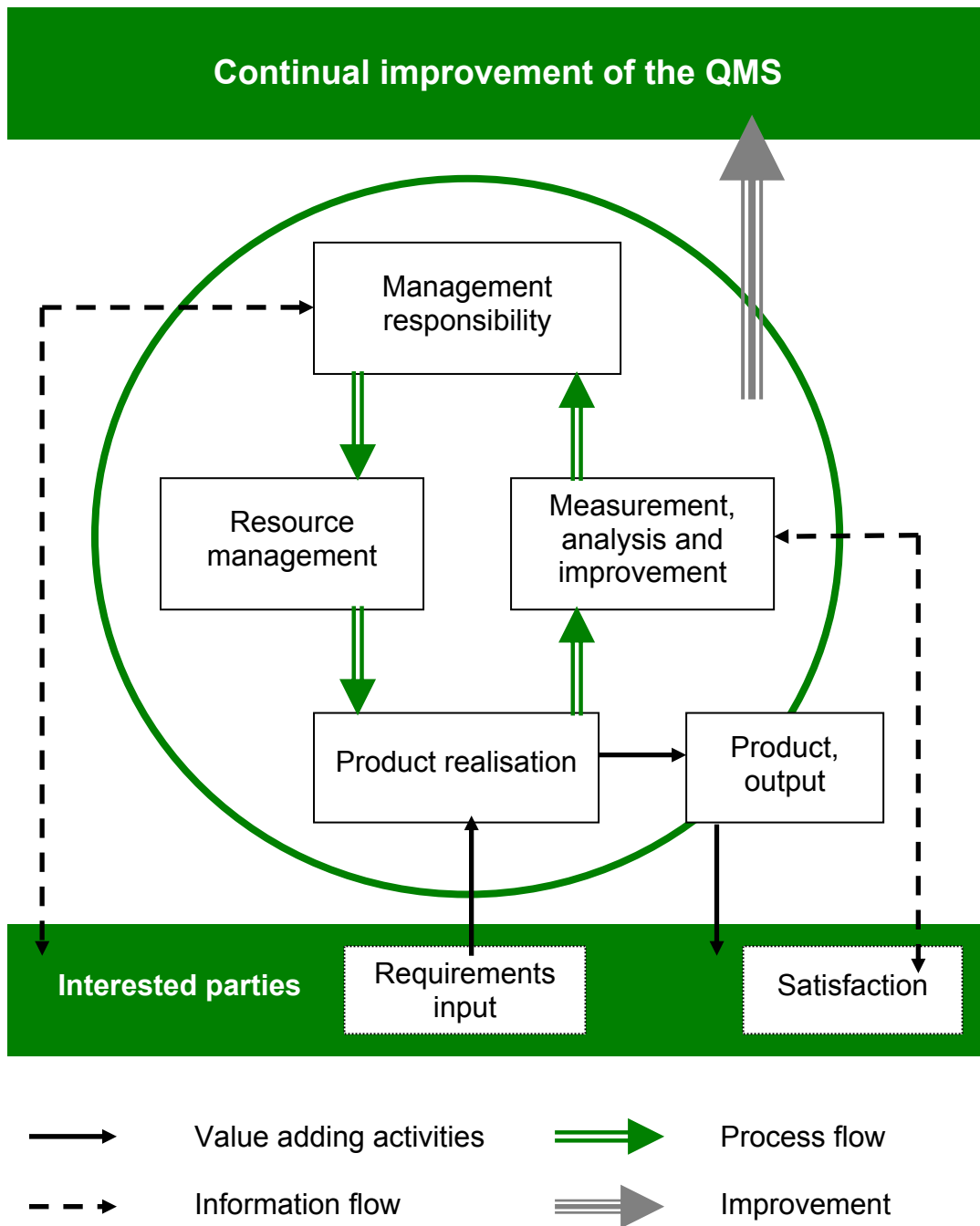
- a) Identifies the processes needed for its operations and their application throughout the organization.
- b) Determines the sequence and interaction of these primary processes (Ref. Figure 1), Interaction of Processes and the [Process interaction matrix](#) (Ref. Appendix E).
- c) Determines criteria and methods needed to make sure that both the operation and management of these processes are effective.
- d) Ensures the availability of resources and information necessary to support the operation and monitoring of these processes.
- e) Ensures monitoring, measurement and analyses of these processes.
- f) Ensures implementation of actions necessary to achieve planned results and continual improvement of these processes.

Cynergin Consultants Ltd. manages these processes in accordance with the requirements of [all applicable standards](#).

Where any processes that affect product conformity with requirements are outsourced, Cynergin Consultants Ltd. ensures management of such processes. Methods of management of such outsourced processes are identified within the QMS as detailed in the [Subcontractor selection procedure](#) (Ref. Appendix F).

Processes needed for the QMS referred to previously include processes for management activities, provision of resources, product realisation and measurement.

Figure 1 Model of a Process-Based QMS



Document 1002 Revision 00

The current revision of this document is located on the Cynerg Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

4.2 Documentation requirements

4.2.1 General

Cynergin Consultants Ltd. QMS documentation includes:

- a) This QMS manual.
- b) Documented statements of the quality policy as detailed in the [Quality policy display](#) (Ref. Appendix A).and quality objectives as detailed in the [BPI matrix](#) (Ref. Appendix B).
- c) Documented procedures required by [all applicable standards](#).
- d) Documents needed by the organization to ensure the effective planning, operation and management of its processes as detailed in the [Documentation master list](#) (Ref. Appendix C).
- e) Records required by [all applicable standards](#) as detailed in the [Records procedure](#) (Ref. Appendix D).

Where the term *documented procedure* appears within this QMS manual, the procedure is established, documented, implemented and maintained.

The extent of the Cynergin Consultants Ltd's QMS is based on the:

- a) Size of the organization and type of its activities.
- b) Complexity of processes and their interactions as detailed in the [Process interaction matrix](#) (Ref. Appendix E).
- c) Competence of personnel as detailed in the [Training procedure](#) (Ref. Appendix G).

Cynergin Consultants Ltd. maintains its documents on various media such as paper, electronic, magnetic, etc.

4.2.2 QMS manual

Cynergin Consultants Ltd has established and maintains this QMS manual that includes:

- a) The scope of the QMS, including details of and justification for any exclusions as detailed in the [Application section](#) of this QMS manual,
- b) Reference to the documented procedures established for the QMS.
- c) A description of the interaction between the processes of the QMS as given in Para. 4.1. Fig. 1 and the [Process interaction matrix](#) (Ref. Appendix E).

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

4.2.3 Management of documents

Documents required by the QMS are managed as detailed in the [Documentation management procedure](#) (Ref. Appendix H). Records are a special type of document and are managed as detailed in the [Records procedure](#) (Ref. Appendix D).

The [Documentation management procedure](#) (Ref. Appendix H) is established to define the means needed to:

- a) Approve documents for adequacy before issue.
- b) Review and update as necessary and re-approve documents.
- c) Make sure that changes and the current revision status of documents are identified.
- d) Make sure that relevant versions of applicable documents are available at points of use.
- e) Make sure that documents remain legible and readily identifiable.
- f) Make sure that documents of external origin are identified and their distribution managed using the [Documentation master list](#) (Ref. Appendix C).
- g) Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.4 Management of records

Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the

QMS. Mechanisms are established for records to remain legible, readily identifiable and retrievable. A documented [Records procedure](#) (Ref. Appendix D) is established to define the means needed for the identification, storage, protection, retrieval, retention time and disposition of records.

5 Management Responsibility

5.1 Management commitment

The Management Team of Cynergin Consultants Ltd. provides its commitment to the development and implementation of the QMS and continually improving its

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

effectiveness by:

- a) Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements as detailed in the [Training procedure](#) (Ref. Appendix G) and the [Communication procedure](#) (Ref. Appendix K).
- b) Establishing the quality policy as detailed in the [Quality policy display](#) (Ref. Appendix A).
- c) Make sure that quality objectives are established as detailed in the [BPI matrix](#) (Ref. Appendix B).
- d) Conducting management reviews as detailed in the [Management review procedure](#) (Ref. Appendix L).
- e) Make sure that the availability of resources as detailed in the [Resource management procedure](#) (Ref. Appendix M).

5.2 Customer focus

The Management Team of Cynergin Consultants Ltd. makes sure that customer requirements are determined and fulfilled with the objective of enhancing customer satisfaction as detailed in the [Subcontractor selection procedure](#) (Ref. Appendix F).

5.3 Quality policy

The Management Team of Cynergin Consultants Ltd. makes sure that Cynergin Consultants Ltd's. quality policy is documented in the [Quality policy display](#) (Ref. Appendix A) and It:

- a) Is appropriate to the purpose of Cynergin Consultants Ltd's activities.
- b) Includes commitments to comply with requirements of [all applicable standards](#) and regulations and continually improve the effectiveness of the QMS.
- c) Provides a framework for establishing and reviewing quality objectives as detailed in the [BPI matrix](#) (Ref. Appendix B) and the [Management review procedure](#) (Ref. Appendix L).
- d) Is communicated and understood within the organization as detailed in the [Training procedure](#) (Ref. Appendix G) and the [Communication procedure](#) (Ref. Appendix K).
- e) Is reviewed for continuing suitability as detailed in the [Management review procedure](#) (Ref. Appendix L).

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

5.4. Planning

5.4.1 Quality objectives

The Management Team of Cynergin Consultants Ltd. makes sure that quality objectives, including those needed to meet requirements for product, are established and documented for relevant functions and levels within the organization as detailed in the [Management review procedure](#) (Ref. Appendix L) and the [BPI matrix](#) (Ref. Appendix B). Quality objectives are measurable and consistent with the quality policy.

5.4.2 QMS planning

The Management Team of Cynergin Consultants Ltd. makes sure that:

- a) The planning of the QMS is carried out in order to meet the requirements given in Para. 4.1 of this QMS manual, as well as the quality objectives detailed in the [Management review procedure](#) (Ref. Appendix L) and the [BPI matrix](#) (Ref. Appendix B).
- b) The integrity of the QMS is maintained when changes to the QMS are planned and implemented as detailed in the [Management review procedure](#) (Ref. Appendix L).

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

The Management Team of Cynergin Consultants Ltd. makes sure that the responsibilities and authorities are defined and communicated within the organization as detailed in the [Resource management procedure](#) (Ref. Appendix M) and the [Organizational chart](#) (Ref. Appendix N).

5.5.2 Management representative

The Management Team of Cynergin Consultants Ltd. has appointed the Director of Quality as a management representative and the Quality Process Manager as a deputy management representative who, irrespective of other duties, have responsibility and authority for:

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

- a) Ensuring that processes needed for the QMS are established, implemented and maintained per the [Resource management procedure](#) (Ref. Appendix M).
- b) Reporting to the Management Team on the performance of the QMS and any need for improvement as detailed in the [Management review procedure](#) (Ref. Appendix L).
- c) Ensuring the promotion of awareness of customer requirements throughout the organization as detailed in the [Communication procedure](#) (Ref. Appendix K).

Responsibilities of the Management Representative also include liaison with external parties on matters relating to the QMS.

5.5.3 Internal communication

The Management Team of Cynergin Consultants Ltd. makes sure that the appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the QMS as detailed in the [Communication procedure](#) (Ref. Appendix K).

5.6 Management review

5.6.1 General

The Management Team of Cynergin Consultants Ltd. reviews the organization's QMS as detailed in the [Management review procedure](#) (Ref. Appendix L). The Management Team conducts these reviews on at least a quarterly basis to ensure continuing suitability, adequacy and effectiveness of the QMS. This review includes assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives.

Records of management reviews are maintained as detailed in the [Records procedure](#) (Ref. Appendix D).

5.6.2 Review Input

The input to management review, as detailed in the [Management review procedure](#) (Ref. Appendix L), includes, as a minimum, information on:

- a) Results of audits.
- b) Customer feedback.

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

- c) Process performance and product conformity.
- d) Status of preventive and corrective actions.
- e) Follow-up actions from previous management reviews.
- f) Planned changes that could affect the QMS.
- g) Recommendations for improvement.

5.6.3 Review output

The output from the management review, as detailed in the [Management review procedure](#) (Ref. Appendix L) as a minimum, includes any decisions and actions related to:

- a) Improvement of the effectiveness of the QMS and its processes.
- b) Improvement of product related to customer requirements.
- c) Resource needs.

6 Resource Management

6.1 Provision of resources

The Management Team of Cynergin Consultants Ltd. determines and provides the resources as detailed in the [Resource management procedure](#) (Ref. Appendix M) to:

- a) Implement and maintain the QMS and continually improve its effectiveness.
- b) Enhance customer satisfaction by meeting customer requirements.

6.2 Human resources

6.2.1 General

The Management Team of Cynergin Consultants Ltd. makes sure that personnel performing work that affects quality of product are competent on the basis of appropriate education, training, skills and experience as detailed in the [Resource management procedure](#) (Ref. Appendix M) and the [Training procedure](#) (Ref. Appendix G).

6.2.2 Competence, awareness and training

Cynergin Consultants Ltd:

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

- a) Determines the necessary competence of personnel performing work affecting product quality as detailed in the [Resource management procedure](#) (Ref. Appendix M).
- b) Provides training or takes other actions to satisfy these needs as detailed in the [Training procedure](#) (Ref. Appendix G).
- c) Evaluates the effectiveness of the actions taken as detailed in the [Resource management procedure](#).
- d) Makes sure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives as detailed in the [Training procedure](#) (Ref. Appendix G).
- e) Maintains appropriate records of education, training, skills and experience as detailed in the [Resource management procedure](#) (Ref. Appendix M). and the [Records procedure](#) (Ref. Appendix D).

6.3 Infrastructure

Cynergin Consultants Ltd. determines, provides and maintains the infrastructure needed to achieve conformity to product requirements as detailed in the [Infrastructure procedure](#) (Ref. Appendix P). Infrastructure includes, as applicable:

- a) Buildings, workspace and associated utilities.
- b) Process equipment, both hardware and software.
- c) Supporting services such as transport or communication.

6.4 Work environment

Cynergin Consultants Ltd. has determined and manages the work environment needed to achieve conformity to product requirements as detailed in the [Infrastructure procedure](#) (Ref. Appendix P).

7 Product Realisation

7.1 Planning of product realisation

Cynergin Consultants Ltd. plans and develops the processes needed for product realisation as detailed in the [Service delivery procedure](#) (Ref. Appendix Q). Planning of product realisation is consistent with the requirements of the other processes of the QMS as given in Para. 4.1. In planning product realisation,

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

Cynergin Consultants Ltd. determines the following, as appropriate:

- a) Quality objectives and requirements for the product as detailed in the [Service delivery procedure](#) (Ref. Appendix Q).
- b) The need to establish processes, documents, and provide resources specific to the product as detailed in the [Service delivery procedure](#).
- c) Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance as detailed in the [Service delivery procedure](#).
- d) Records needed to provide evidence that the realisation processes and resulting product fulfil requirements as detailed in the [Records procedure](#) (Ref. Appendix D).

The output of this planning is documented as detailed in the [Service delivery procedure](#).

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

Cynergin Consultants Ltd. determines the [Service delivery procedure](#) (Ref. Appendix Q) as:

- a) Requirements specified by the customer, including the requirements for delivery and post-delivery activities,
- b) Requirements not stated by the customer but necessary for specified or intended use, where known.
- c) Statutory and regulatory requirements related to the product.
- d) Any additional requirements determined by the organization.

7.2.2 Review of requirements related to the product

Cynergin Consultants Ltd. reviews the requirements related to the product as detailed in the [Service delivery procedure](#). This review is conducted before Cynergin Consultants Ltd. commitment to supply a product to the customer. It relates to such activities as submission of tenders, acceptance of contracts or orders and acceptance of changes to contracts or orders. This review ensures that:

- a) Product requirements are defined in the [Service delivery procedure](#). (Ref. Appendix Q).

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

- b) Contract or order requirements differing from those previously expressed are resolved.
- c) Cynergin Consultants Ltd. has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review are maintained as detailed in the [Service delivery procedure](#) and the [Records procedure](#) (Ref. Appendix D)..

Where the customer provides no documented statement of requirement, the customer requirements are confirmed by Cynergin Consultants Ltd. before acceptance. Cynergin Consultants Ltd. maintains records of communication regarding such requirements as detailed in the [Service delivery procedure](#) and the [Records procedure](#).

Where product requirements are changed, Cynergin Consultants Ltd. make sure that the relevant documents are amended and that relevant personnel are made aware of the changed requirements as detailed in the [Service delivery procedure](#).

7.2.3 Customer communication

Cynergin Consultants Ltd. has determined and implemented effective arrangements for communicating with customers in relation to:

- a) Product information as detailed in the [Marketing procedure](#) (Ref. Appendix R).
- b) Inquiries, contracts or order handling, including amendments as detailed in the [Service delivery procedure](#) (Ref. Appendix Q).
- c) Customer feedback, including customer complaints as detailed in the [Post marketing surveillance procedure](#) (Ref. Appendix S) and the [NC-CAPA procedure](#) (Ref. Appendix T).

7.3 Design and development - exclusion

Cynergin Consultants Ltd. provides consulting services and does not design or produce tangible products; therefore this clause is not applicable to the QMS. When outsourced design function is required, Cynergin Consultants Ltd. manages this process as detailed in the [Subcontractor selection procedure](#) (Ref. Appendix F).

7.4 Purchasing - exclusion

Cynergin Consultants Ltd. provides consulting services and does not produce tangible products; therefore this clause is not applicable to the QMS.

7.5 Production and service

7.5.1 Management of production and service - exclusion

Cynergin Consultants Ltd. provides consulting services and does not produce tangible products; therefore this clause is not applicable to the QMS.

7.5.2 Validation of processes for production and service - exclusion

Cynergin Consultants Ltd. provides consulting services and does not produce tangible products; therefore this clause is not applicable to the QMS.

7.5.3 Identification and traceability - exclusion

Cynergin Consultants Ltd. provides consulting services and does not produce tangible products; therefore this clause is not applicable to the QMS.

7.5.4 Customer property

Cynergin Consultants Ltd. exercises care with customer property while it is under the organisation's management or being used by the organisation. Cynergin Consultants Ltd. identifies, verifies, protects and safeguards customer property provided for use or incorporation into the product as detailed in the [Service delivery procedure](#) (Ref. Appendix Q). If any customer property is lost, damaged or otherwise found to be unsuitable for use, it is reported to the customer as detailed in the [NC-CAPA procedure](#) (Ref. Appendix T). Records of such reports are maintained as detailed in the [Records procedure](#) (Ref. Appendix D).

7.5.5 Preservation of product - exclusion

Cynergin Consultants Ltd. provides consulting services and does not produce tangible products; therefore this clause is not applicable to the QMS.

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

7.6 Management of measuring and monitoring devices

Cynergin Consultants Ltd. determines the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements as detailed in the [Measuring equipment procedure](#) (Ref. Appendix U).

Cynergin Consultants Ltd. has established processes to make sure that monitoring and measurement can be achieved in a manner that is consistent with the monitoring and measurement requirements. Where necessary to ensure valid results, measuring equipment is:

- a) Calibrated or verified 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.
- b) Adjusted or re-adjusted as necessary.
- c) Identified with its calibration status.
- d) Safeguarded from adjustments that would invalidate the measurement result.
- e) Protected from damage and deterioration during handling, maintenance and storage.

Cynergin Consultants Ltd. assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements as detailed in the [Measuring equipment procedure](#) (Ref. Appendix U). Cynergin Consultants Ltd. takes appropriate action on the equipment and any product affected per the [NC-CAPA procedure](#) (Ref. Appendix T). Records of the results of calibration and verification are maintained as detailed in the [Records procedure](#) (Ref. Appendix D).

8 Measurement, Analysis and Improvement

8.1 General

Cynergin Consultants Ltd. plans and implements the monitoring, measurement, analysis and improvement processes as detailed in the [Management review procedure](#) (Ref. Appendix L) and the [BPI matrix](#) (Ref. Appendix B) to.

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

- a) Demonstrate conformity of the product.
- b) Ensure conformity of the QMS.
- c) Continually improve the effectiveness of the QMS.

This includes determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

Cynergin Consultants Ltd. has established, as one of the measurements of the performance of the QMS, monitoring of information related to customer perception as to whether Cynergin Consultants Ltd. has achieved customer requirements. The methods for obtaining and using this information are determined in the [Post marketing surveillance procedure](#) (Ref. Appendix S) and the [NC-CAPA procedure](#) (Ref. Appendix T).

8.2.2 Internal audits

Cynergin Consultants Limited conducts internal audits at planned intervals as detailed in the [Audit procedure](#) (Ref. Appendix V) to determine whether the QMS:

- a) Conforms to the planned arrangements, to the requirements of [all applicable standards](#) and QMS requirements established by Cynergin Consultants Ltd.
- b) Is effectively implemented and maintained.

Cynergin Consultants Ltd. plans the audit program 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. Selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process. Auditors do not audit areas of their own responsibilities.

The responsibilities and requirements for planning and conducting audits and for reporting results are defined in the [Audit procedure](#) and records are maintained as detailed in the [Records procedure](#) (Ref. Appendix D).

The management responsible for the area audited ensures that actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results per the [NC-CAPA procedure](#) (Ref. Appendix T).

For its auditing activities, Cynergin Consultants Ltd. uses for guidance ISO 19011 - Guidelines for quality and/or environmental management systems auditing,

8.2.3 Monitoring and measurement of processes

Cynergin Consultants Ltd. applies suitable methods for monitoring and, where applicable, measurement of the QMS processes as detailed in the [BPI matrix](#) (Ref. Appendix B). These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, corrective action is taken, as appropriate, to ensure conformity of the product as detailed in the [NC-CAPA procedure](#) (Ref. Appendix T).

8.2.4 Monitoring and measurement of product

Cynergin Consultants Ltd. monitors and measures the characteristics of the product to verify that product requirements are met. This is carried out at appropriate stages of the product realisation process in accordance with the planned arrangements as detailed in the [Service delivery procedure](#) (Ref. Appendix Q), [Post market surveillance procedure](#) (Ref. Appendix S) and the [NC-CAPA procedure](#) (Ref. Appendix T).

Evidence of conformity with the acceptance criteria is maintained as detailed in the [Records procedure](#) (Ref. Appendix D). Records indicate the person(s) authorizing release of product.

Product release and service delivery does not proceed until the planned arrangements have been satisfactorily completed as detailed in the [Service delivery procedure](#) (Ref. Appendix Q) unless otherwise approved by a relevant authority as detailed in the [NC-CAPA procedure](#) (Ref. Appendix T) and where applicable by the customer as detailed in the [Service delivery procedure](#).

8.3 Management of non-conforming product

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

Cynergin Consultants Ltd. has established and maintains a documented [NC-CAPA procedure](#) (Ref. Appendix T) to make sure that product that does not conform to product requirements is identified and managed to prevent unintended use or delivery. This process identifies related responsibilities and authorities for dealing with non-conforming product.

Cynergin Consultants Ltd. processes non-conforming product by one or more of the following ways:

- a) Taking action to eliminate the detected non-conformity.
- b) Authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer.

Records of the nature of non-conformities and any subsequent actions taken, including concessions obtained, are maintained as detailed in the [Records procedure](#) (Ref. Appendix D).

When non-conforming product is corrected, it is subject to re-verification to demonstrate conformity to the requirements as detailed in the [NC-CAPA procedure](#) (Ref. Appendix T).

When non-conforming product is detected after delivery or use has started, Cynergin Consultants Limited takes action appropriate to the effects, or potential effects, of the non-conformity as detailed in the [NC-CAPA procedure](#).

8.4 Analysis of data

Cynergin Consultants Ltd. has established and maintains documented [Management review procedure](#) (Ref. Appendix L) and the [BPI matrix](#) (Ref. Appendix B) to determine collect and analyze appropriate data to determine the suitability and effectiveness of the QMS to evaluate areas where continual improvements of the effectiveness of the QMS can be made. This includes data generated by monitoring and measurement and other relevant sources. Cynergin Consultants Ltd. analyzes these data to provide information related to:

- a) Customer satisfaction as detailed in the [Post market surveillance procedure](#) (Ref. Appendix S) and the [NC-CAPA Procedure](#) (Ref. Appendix T).
- b) Conformity to product requirements as detailed in the [Service delivery procedure](#) (Ref. Appendix Q) and the [NC-CAPA procedure](#).

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

- c) Characteristics and trends of process and products including opportunities for preventive action as detailed in the [NC-CAPA procedure](#).
- d) Suppliers as detailed in the [Subcontractor selection procedure](#) (Ref. Appendix F) and the [NC-CAPA procedure](#) (Ref. Appendix T).

8.5 Improvement

8.5.1 Continual improvement

Cynergin Consultants Ltd. has established and maintains documented procedures to continually improve its QMS through the use of the:

- a) Quality policy as detailed in the [Quality policy display](#) (Ref. Appendix A).
- b) Quality objectives as detailed in the [BPI matrix](#) (Ref. Appendix B).
- c) Audit results as detailed in the [Audit procedure](#) (Ref. Appendix V).
- d) Analysis of data as detailed in the [BPI matrix](#).
- e) Corrective and preventive actions as detailed in the [NC-CAPA procedure](#) (Ref. Appendix T).
- f) Management review as detailed in the Management review procedure.

8.5.2 Corrective action

Cynergin Consultants Ltd. has established and maintains a documented [NC-CAPA Procedure](#) to eliminate the causes of non-conformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the non-conformities encountered. The [NC-CAPA Procedure](#) defines requirements for:

- a) Reviewing non-conformities, including customer complaints.
- b) Determining the causes of non-conformities.
- c) Evaluating the need for action to ensure that non-conformities do not recur.
- d) Determining and implementing action needed.
- e) Records of the results of action taken.
- f) Reviewing corrective action taken.

8.5.3 Preventive action

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

Cynergin Consultants Ltd. has established and maintains a documented [NC-CAPA procedure](#) (Ref. Appendix T) to eliminate the causes of potential non-conformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems. The [NC-CAPA procedure](#) defines requirements for:

- a) Determining potential non-conformities and their causes.
- b) Evaluating the need for action to prevent occurrence of non-conformities.
- c) Determining and implementing action needed.
- d) Recording results of action taken.
- e) Reviewing preventive action taken.

Appendix A - Quality Policy Display

Our aim is to ensure that our customers never need to contemplate an alternative solution.

To do this, our products and services must always anticipate and meet our customers' expectations. Customers buy from us when we deliver what they want, faster and better than our competitors and at the price they are willing to pay.

Similarly, a customer's experience of Cynergin has to be consistent, irrespective of when they interact with the company, who they speak to or where they are located.

Quality Management provides the framework for both consistently delivering high quality products and services and for our ongoing program of continual review and improvement.

Quality is a way of working that promotes best practice and high efficiency and effectiveness. It touches every aspect of what we do.

Through our quality management system, our standards and work practices are documented and our people understand their intent and know how to put them into practice.

Just as every employee is responsible for the success of the company, every employee is responsible for quality. Our aim is for every employee to embrace our corporate commitment to quality and continual improvement and to understand their role and how they contribute.

Our Quality Management System is certified to ISO 9001:2000



www.cynerginconsultants.com

Quality Policy

The management team of Cynergin Consultants Limited and all its employees and consultants are committed to the quality of our services and our stated quality objectives.

We are striving to achieve the industry's leading position in quality of our products and services;

We will maintain a quality management system to meet the requirements of the ISO 9001:2000 standard;

We will continually improve the effectiveness of our quality management system and the level of customer satisfaction;

Our employees and consultants will recognise our company as the best company to work for in our chosen fields;

We will maintain a profitable operation to establish our competitive position in the market and reward our shareholders;

We will meet the needs and expectations of all our stakeholders; and

The management team will periodically review the performance of the quality management system and our quality objectives to ensure their effectiveness and continuing suitability.

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

Appendix B - BPI Matrix

TBI

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

Appendix C - Document Master List TBI

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

Appendix D - Records Procedure

A records procedure is required to specify

- which records are kept
- by whom
- for how long
- how they are disposed of.
-

The following clauses of ISO 9001 contain the instruction "...see 4.2.4 which means that you must retain these records

5.6.1 Management review minutes

6.2.2 Records of education, training, skills and experience

7.1 Evidence that the realization processes and product fulfil requirements

7.2.2 Records of sales activities

7.3.2 Design and development inputs

7.3.4 Design and development reviews and any related actions

7.3.5 Design and development verification and any related actions

7.3.6 Design and development validation and any related actions

7.3.7 Design and development changes and any related actions

7.4.1 Results of supplier evaluations and any actions arising

7.5.2 Records to demonstrate the validation of special processes

7.5.3 Where traceability is required, the unique identification of the product is recorded

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

7.5.4 Customer property that is lost, damaged or otherwise found to be unsuitable

7.6 Basis used for calibration of measuring equipment where no international or national standards exist

7.6 Validity of the previous measuring results when measuring equipment is found to be out of calibration

7.6 Results of calibration and verification of measuring equipment

8.2.2 Internal audit results and follow-up actions

8.2.4 Indication of the person(s) authorizing release of product.

8.3 Records of the product nonconformities and any subsequent actions

8.5.2 Results of corrective action

8.5.3 Results of preventive action

Appendix E - Process Interaction Matrix

TBI

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

Appendix F - Subcontractor Selection Procedure

- Sponsor or Peer Reviewed

If the subcontractor is specified in the proposal and the collaboration is funded, it is not necessary to comply with the procurement requirements for competitive bidding or sole source justification since the sponsor or peer review process already approved the selection. If this is not the case, you must comply with the following procedures for selection.

- Non-Sponsor or Non-Peer Reviewed

It is the responsibility of the Cynergin consultant, along with OSP, to comply with procurement requirements of the sponsor in selecting a subcontractor. There are two methods of selecting a subcontractor: competitive bidding or sole source procurement.

Competitive bidding is used as the normal method of subcontractor selection. This method requires OSP, in conjunction with the Cynergin consultant, to solicit proposals from a number of sources and make a final selection of a subcontractor from those responding based on technical merit and cost objectives, normally the lowest price from a technically qualified respondent.

When the procurement requires performance from a sole entity because services or expertise are not available from other sources, the Cynergin consultant is required to provide sole source justification, identifying the need for the services and why the selected subcontractor is the only source available for the needed services. Sole source selection is not justified simply by the fact that there has been an ongoing collaboration between the scientists. It must be further justified with reasons for the unavailability of the services or expertise from other sources.

Regardless of the method used in selecting a subcontractor, there must be adequate time provided between the receipt of a subcontractor's proposal and the Sponsor's proposal due date, to allow the Cynergin Consultant sufficient time to discuss and negotiate the statement of work.

A budget, itemized by major budget category, such as salaries and wages, employee benefits, supplies, equipment, travel, consultants, subcontractors and other direct costs, is submitted by the subcontractor as part of its proposal. Greater itemization of categories

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

may be needed if required by the prime agreement. Facilities and administrative costs (indirect costs) should be included and should be calculated using the subcontractor's current rate(s). A copy of the subcontractor's negotiated rate agreement is needed to verify the costs requested and to support those costs in case of an audit. If the subcontractor uses a rate for employee benefits, a copy of that rate agreement will also be needed.

The subcontractor's proposal must be signed by a designated official who is authorized to commit the subcontractor's resources to the completion of the project.

Appendix G - Training Procedure

1. Purpose

To establish and define an internal training program and to make sure that company personnel are competent. Training and training verification are key factors for successful company operations.

2. Scope

This training procedure is used to make sure that training has taken place with each employee for procedures and methods that the employee performs. The procedure applies to on-the-job training, in-house training and new-employee training. The training is verified and documented. The training procedure is applicable to new employees, for the introduction of new procedures and methods, for retraining of employees, and for verification of employee performance.

3. Responsibilities

A. Second Level Manager:

- ensures implementation of the training procedure
- ensures resources are allocated for identified training within budgetary constraints
- responsible for the evaluation, training and growth of the technical and quality related skills of employees by establishing training schedule and rotation for all new employees and by ensuring personnel receive training and demonstrate competence
- ensures training is accomplished
- submits documentation for completed training for entry into the training database or Integrated Management of Personnel
- identifies training needs and courses and submits financial bids before the fiscal year budget.

B. First Level Manager:

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

- implements training and maintains employee training files
- ensures proper supervision of trainees until training completed
- reviews training received and ensures training files are complete
- submits documentation for training completed
- monitors employee performance to identify the need for retraining or additional continual education
- identifies training needs resulting from new or revised procedures and processes.

C. Quality Management Systems (QMS) Manager:

- trains employees in quality control and quality assurance procedures.

D. Staff:

- completes required training within specified timeframe
- becomes and stays knowledgeable in procedures and methods performed
- are responsible for self-training, through reading current literature and technical papers
- reports all training received and submits documentation for training received
- reads and complies with standards, regulations, policies, procedures, and work instructions.

Appendix H - Document Management Procedure TBI

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

Appendix J - Document Master List

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

Appendix K - Communications Procedure

Internal Communication

Internal communications shall be conducted to assist with the acceptance, implementation and operation of the management system. In addition to formal management review meetings, the Quality Assurance Manager will hold regular staff meetings at appropriate intervals to review processes, inform staff of the effectiveness of the Quality System, review Customer feedback, carry out preventive action (risk analysis) communicate the organisations commitment to meeting customers' needs and ensure staff are familiar with the companies legal and regulatory obligations.

Company objectives will be verified, and the continued suitability, adequacy and effectiveness of the company will be discussed.

These meetings will be appropriately documented.

Appendix L - Management Review Procedure

1.0 PURPOSE

The purpose of this procedure is to define the methods used to review the Quality System that is in operation.

2.0 SCOPE

This procedure applies to all Management Review Meetings, including their associated documentation.

3.0 Definition

Management Review Meetings

A structured meeting that must take place at regular intervals to discuss the functioning of the company quality system and to take action to correct it when necessary. Management Review Meetings are designed to make sure that all quality related functions are reviewed at the highest possible level and so that all levels of management affecting quality are made aware of changes, updates revisions, verification activities and policies. The Management Review will take the form of a formal, recorded meeting under the Chairmanship of the Quality Assurance Manager and any other staff designated by senior Management will attend.

Responsibilities

It is the responsibility of the Quality Assurance Manager to conduct regular Management Review Meetings. It is the responsibility of the Quality Assurance Manager to ensure that this procedure is carried out.

Objectives of management review meetings

The objectives of the Management Review are:-

- To establish that the Quality Assurance System is achieving the expected results, continuing to conform to the standard, and functioning in accordance with the established Operating Procedures.
- To expose irregularities or defects in the System, identify weaknesses and make recommendations for continual improvement.

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

- To review the effectiveness of previous corrective actions including those related to subcontractor and supplier performance.
- To review the adequacy and suitability of the Quality Assurance System for current and future operations.
- To review any complaints received, identify the cause and recommend corrective action if required including customer feedback.
- To review the finding of internal / external audits and identify any areas of recurring problems.
- To review the reports of non-conformities and evaluate trend information.
- To review training requirements. Analyse all the above for trends and make appropriate improvements.

Model Review Meeting Agenda

2. Apologies for Absence.
3. Minutes of Previous Meeting.
4. Review of Corrective Actions from Previous meeting.
5. Review of General Actions from Previous Meeting.
6. Changes to the Quality Assurance Standard, Quality Assessment Schedule or Certification Requirements.
7. Review Input Results of audits, customer feedback, performance status of preventive and corrective action
8. Review output Improvement of the effectiveness of the system
Improvements of the service related to customer requirements. resources needed.
9. Proposed Quality Assurance System Improvements/Modifications. (Including objectives and policy).
10. Scheduled Internal Audit Programme.
11. Subcontractor/suppliers performance.
12. Staff training needs review.
13. Review of infrastructure and work environment.

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

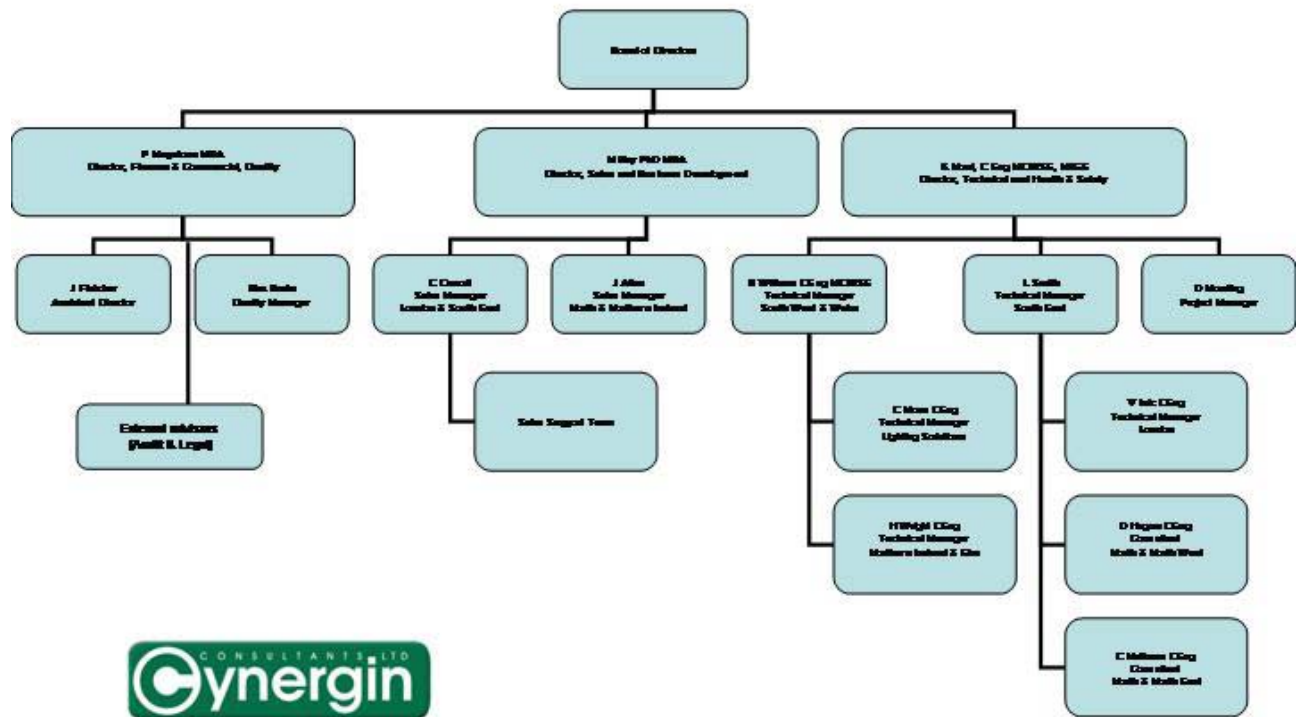
14. Any other business.
15. Date and time of next meeting. The Quality Assurance Manager will produce documentation (including analyses, reviews, proposals, etc.) for circulation to participants. The content of the meetings will be formally documented and recorded by the Quality Assurance Manager.

Appendix M - Resource Management Procedure TBI

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

Appendix N - Organisation Chart



Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

Appendix P - Infrastructure Procedure

TBI

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

Appendix Q - Service Delivery Procedure

1. Why have these procedures been developed?

The policy on staff undertaking consultancy and other work for outside bodies has been approved and adopted by Cynergin Consultants Ltd. These procedures have been developed as a guide for all members of Cynergin Consultants Ltd. who engage in relevant commercial activity governed under the policy, where the resulting contract will be between Cynergin Ltd and the outside body.

2. Who do these Procedures apply to?

These procedures are mandatory for all members of Cynergin Consultants Ltd. who intend to undertake work for an outside body.

Failure to comply with the policy and these procedures may result in appropriate disciplinary action being taken.

2. What is the objective of these procedures?

The procedures aim to manage the risks inherent in undertaking work for a third party. They will also empower employees to be able to enter into commercial agreements on behalf of Cynergin Consultants Ltd. whilst offering the individual staff member(s) the protection of Cynergin Consultants Ltd's expertise and services.

3. What benefits do I get by following the procedures?

The benefits to an individual staff member undertaking work for an outside body on behalf of Cynergin Consultants Ltd. (as opposed to in an individual capacity) would include:

•Personal Liability and Insurance

By virtue of the fact that a contract made through Cynergin Consultants Ltd will be between Cynergin Consultants Ltd. and the third party; the individual, will have the benefit of the Cynergin Consultants Ltd's professional indemnity (and other) insurances.

•Access to Cynergin Consultants Ltd's Professional Services

This includes the range of services the University undertakes in its normal course of business. For example:

Credit checking of third parties

Legal and other specialist advice

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

Ongoing support and advice where required.

4. What are the procedures?

Stage 1 - Quality Assurance

Take into account all commercial considerations.

Are there sufficient quality assurance procedures in place to reasonably ensure that this piece of work will be carried out in the manner prescribed and in the time allowed?

Stage 2 - Costing and Pricing

1. Costing – Project Manager/ Accountant

The costs of undertaking the activity are fully determined and understood.

Establish the full economic costs.

Is the activity liable for VAT or other taxation / duties?

2. Pricing

•

The final pricing decision should be authorised by the Board of Cynergin Consultants Ltd

Stage 3 - Legal / Approval

•If under £100,000 *and*

a. you have received training from the Commercial Department and

b. you are using an unmodified standard agreement prepared by Commercial Department

then the agreement should be signed a Director and

countersigned by the trained person; for example, the Project Manager

•If under £100,000 and the above does not apply then the contract terms must be approved by the Commercial Department. A Director would sign the contract once approved under stages 1 and 2 above, and the Project Manager would countersign.

•If the contract is between £100,000 and £300,000 contract terms must be approved through the Commercial Department and the Board of Cynergin Consultants Ltd.

•If the contract is valued over £300,000 then approval from the Board of Directors.

A checklist has been developed to enable the contract sponsor to monitor at what the stage the contract is up to and to ensure that all necessary steps are taken. The checklist should be attached to the front of any documentation for ease of reference.

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

Appendix R - Marketing Procedure

TBI

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

Appendix S - Post Marketing Surveillance Procedure TBI

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

Appendix T - NC - CAPA Procedure

TBI

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

Appendix U - Measuring Equipment Procedure

1. Purpose

The purpose of this procedure is to specify responsibilities and give guidance on the calibration of monitoring and measuring equipment used by Cynergin Ltd.

2. Scope

This procedure applies to all equipment and instruments used by Cynergin Ltd.

3. Procedures

3.1 Specific Procedures

- a) Inspect the instrument or equipment to make sure that there is no obvious damage and that it is functioning properly.
- b) Follow specific instructions that were previously prepared by the manufacturer and/or the principal operator, which describe in detail how the instrument or equipment should be properly calibrated. Those instructions will contain the frequency of calibration, inspection procedures and the method of calibration in accordance with the manufacturer's specification or recommendation.

3.2 Responsibilities

The individuals responsible for the monitoring and measurement must make sure that instruments used are correctly calibrated.

3.3 Documentation

Calibration efforts shall be documented and retained in accordance company policy and procedures.

Appendix V - Audit Procedure

1.0 Internal audit

An audit of each section of the Quality manual takes place annually, or more frequently should any activity require it, to ensure that quality performance meets customer requirements. An audit schedule will be prepared and distributed in advance by the Quality Assurance Manager as part of quality planning. Internal Auditors will be trained to carry out the work planned in the audit schedules.

Audit reports and non-conformances will be analysed by the Quality Assurance Manager and action taken to eliminate causes of non-conformances and further action to ensure that improvements are made to the system. It is the responsibility of the Quality Assurance Manager to implement these procedures. Auditors will not audit their own responsibilities. Thus audits will be independent and unbiased. Audits will be evaluated at Management Review Meetings and at internal communication meetings.

Generally an audit is a number of tests on the various contracts that occurred during the year. These tests, along with questions and inquiries made by the auditor(s) lead to an opinion about the appropriateness of the contract statements.

The Quality Assurance Manager defines the specific criteria, scope, methods and objectives for the internal audit based on the status, maturity, and importance of specific elements in Cynergin Ltd's quality system.

Audits shall be carried out to a defined scope and shall be as follows,

- a) Planned: as per the internal audit plan
- b) Unplanned: arising as a result of:
 - Customer complaints
 - Following the implementation of actions defined in a corrective action report
 - Following the identification of additional or amended procedures for products.

In planning the particular audit, these activities include determining the extent and boundaries of the audit (locations, activities, processes); set of policies, procedures and/or requirements to be audited against; auditing methods; and audit objectives.

The Quality Assurance Manager selects the appropriate auditor to ensure objectivity and impartiality of the audit process.

The Quality Assurance Manager and the auditor review the proposed audit program to ensure that it is consistent with and effective for the defined audit criteria, scope, methods, and objectives.

Before the audit date, auditor reviews the appropriate quality system documentation, records of completed corrective and preventive actions, and past audit findings for the

Document 1002 Revision 00

The current revision of this document is located on the Cynergin Consultants Ltd. network/website. It is the responsibility of the user to make sure that they are using the latest revision.

activities to be audited, and then develops a checklist covering the quality system elements and activities to be audited.

2 INTERNAL QUALITY AUDIT INVESTIGATION

The auditor will contact the personnel in the area being audited at the time indicated on the audit program, and briefly review the audit criteria, scope, methods and objectives with them.

NOTE :

The checklists only serve as a guide to the auditors, and other areas may be investigated as deemed necessary by the auditors or as requested by the auditee.

- 1 When a nonconformance is identified, the auditor presents the nature of the nonconformity and the evidence to the personnel involved for verification, clarification, and addresses any questions or concerns that the personnel may have, as well as to give advice, when requested, regarding any problems which are uncovered.
- 2 If the non-conformance is confirmed, then go to step 4
- 3 If the possible non-conformance requires further clarification the auditor will discuss the situation with the Quality Assurance Manager.
- 4 After the facts of the nonconformity are verified (or modified), the auditor either drafts a non-conformance statement or documents the necessary information for writing one later.

NOTE :

The non-conformance statement includes the nature of the nonconformity, the factual evidence obtained, and the nature of the requirement that is not being complied with (i.e., the appropriate ISO 9001 clause number, the appropriate quality system document section/page/paragraph, what the personnel says is the normal practice, contract requirements, statutory regulations, current standards, and any other relevant requirements).

3 REPORTING AND FOLLOW-UP

Within 1 week of completing the internal audit program, the auditor prepares a brief internal audit report and submits it to The Quality Assurance Manager for review and approval.