# Quality Manual

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<td>Prepared by</td>
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Introduction

1. Scope of Services
The Estates Department is a Department of the HSE West Area that is responsible for providing expert advice and support in relation to technical issues, including estate management, energy management, fire safety, technical training compliance auditing, quality assurance, value for money, and standard setting so as to ensure effective implementation of policy and legislation and to manage selected projects in consultation with line management.

The scope of the audit is to include Capital projects, Maintenance, Fire Safety, Quality Management and Corporate Management.

2. Exclusions and rationale
The following permissible exclusions apply to the Quality Manual System as implemented by the Organisation are as follows:

7.5.2 Validation of product
HSE Estates West do not have any product/ service that requires validation. This clause is not applicable to the Organisation.

3. Distribution of the Quality Manual
The Documents are available to all through their direct line Manager on the computer network.


The Quality Manual is controlled, approved and distributed in accordance with the Organisation's document control procedure.

5. Organisation History

The HSE was established in 2005. The former Mid Western Health Board Estates Department became the Estates Department of the HSE Mid Western Area at this stage.

6. Organisational Chart

See Appendix C for Organisation chart.
7. Legal, Regulatory Requirements and International/ National Standards

The Organisation have a controlled list of Legal and Regulatory, National and International Standards in place.


8. Core Processes

The Core processes of the Organisation include:

Capital projects.
Those involved in capital projects aim to ensure that new developments and new facilities, or the upgrade and enhancement of existing ones are carried out in a controlled manner in line with statutory regulations, within defined standards of cost, time, performance and quality. This includes equipping function also.

Maintenance
Maintenance refers to maintenance of building infrastructure and equipping including biomedical and planned equipment replacement. Maintenance Departments are generally located on site.
Fire Safety
This process includes fire safety inspections, reports, advise, training and liaison with statutory bodies with regard to the fire safety aspects of our buildings. All master files are held primarily in Head Office, Plassey, with the Fire Officer.

Quality Management
The Quality management aspect includes Control, management and ongoing review of our quality management system. Relevant records are held in Head Office, Plassey.

Corporate Management
Corporate Management includes financial control and processing, energy management, property management and strategic planning.

Supporting Procedures

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4. Quality Management System

4.1 General Requirements

HSE- Mid Western Area ESTATES DEPARTMENT has established, documented, implemented and maintains a Quality Management system (QMS) in accordance with the requirements of ISO 9001:2000. This system intends to be continuously improved in effectiveness through use of the following methods:

- Customer focus
- Internal auditing
- Continuous process improvement
- Structured Management Review
- Corrective and Preventative action

THE HSE ESTATES DEPARTMENT is committed to adhering and improving the QMS at all times. THE HSE ESTATES DEPARTMENT has

- Identified all major processes steps and critical operations within each step are involved in the end-to-end operation of our business. In addition to core operational processes these include:
  - Management Activities
  - Resource Provision
  - Product Realisation
  - Measurement, Analysis and Improvement

- Documented procedures as deemed necessary in accordance with each process identified throughout the Organisation
- Reviewed in detail the sequencing and inter relationship between each process step
- Established measures that allow use to ensure that the operation of each process step is effective
- Commitment that adequate resources will be made available towards the operation of the process steps.
- Committed that we will provide relevant and timely information as will allow for the monitoring of the processes.
- Commitment to implementation of all necessary
  - Corrective action to achieve planned results
  - Process Improvement – to address customer and Strategic issues
4.2 Documentation Requirements

4.2.1 General

THE HSE ESTATES DEPARTMENT Quality Management System includes:
Our Quality Policy that has the full support of both Management and Employees of HSE - ESTATES WEST. The statement is posted in the Reception area. The HSE West Area Quality Policy is to provide a high standard of service throughout its operations.

This will involve carrying out Estate Management, Maintenance Programmes, Fire Safety, Technical Training, Asset management, Design and Management of selected projects, and Technical Support within the Statutory, Planning and Quality Framework that informs the delivery of these services, and which is detailed in the Estates Operational Plan.

- Documented Quality Objectives: The Business and/ or Quality Objectives of THE HSE ESTATES DEPARTMENT are formally documented and reviewed as part of the Management Review process. These objectives are based on the analysis of data, including feedback on all aspects of product/ service, Customer requirements and contract information, market needs, service delivery data and information relating to competition or “best in class” performers, where appropriate. Attainment of these goals or objectives is dependent on the identification, implementation and continuous improvement of the Organisation processes. These objectives are communicated to all members of the Organisation and generally encompass the product or service itself, process/ and/or cost, delivery and service elements, as the Business requires. Progress with respect to objectives is also periodically reviewed, informally.
- Procedures and records required by the International Standard
- Processes required by the Business.

Refer to: Appendix D: Interaction between the processes of the Quality Management System.

4.2.2 Quality Manual

THE HSE ESTATES DEPARTMENT has documented a Quality Manual, which documents the relationship between the ISO 9001:2008 standard and development within the Organisation. The scope and any requirements or clauses within requirements that are not applicable to this Organisation are clearly visible throughout the manual and are also noted in the introduction section. The Manual highlights the documented procedures and processes established for the QMS and also their sequence/ interaction.
4.2.3 Control of Documents

The documentation and data control is designed to provide for the following:

- Approval of documents for adequacy prior to issue
- Review, updating and approval of documents, as necessary
- To ensure that changes and the current revision status of documents are identified
- To ensure that relevant versions of applicable documents are available at the point of use
- To ensure that documents remain legible and readily identifiable
- To ensure that documents of external origin are identified and their distribution controlled
- To prevent unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose

A master list of documents is maintained. All original documents are maintained in the Master folder. If the original document is revised amended or discontinues, the original document will be marked “obsolete” and stored in the obsolete folder. The revised or amended version of the original document will be marked “master” and placed in the master folder.

Refer to Procedure No 301 Document and Data Control for further details

4.2.3 Control of Quality Records

Quality records as required by the Quality Management System have been identified and are recorded and stored in a manner that ensures that the integrity of the records is maintained. These records shall be legible, identifiable and retrievable. The Quality Manual and/or relevant procedures define the records maintained as a result of the process in operation. A master list of records is maintained that specifies period of retention. All Quality Records will be retained as per listings.

Refer to Procedure No 302 Record Control for further details
5. Management Responsibility

5.1 Management Commitment

In understanding the need for a defined Quality and Business processes to ensure effective control of Quality Practices, the Management team at THE HSE ESTATES DEPARTMENT has committed to using ISO 9001:2008 as a standard against which the documented processes and our overall QMS will be measured.

The ISO 9001:2000 standard sets a more focused approach to Customer Requirements as well a statutory and regulatory requirements. The Management Team at THE HSE ESTATES DEPARTMENT continuously communicate the importance of Customer Requirements. Our Quality Objectives also highlight the importance of Customer requirement throughout. THE HSE ESTATES DEPARTMENT Management Team is fully committed to the Quality Policy, which is reviewed for effectiveness at the Management Review meetings. Management Reviews are conducted at least annually. Resources are constantly reviewed by Management to ensure that objectives are achieved.

5.2 Customer Focus

THE HSE ESTATES DEPARTMENT regards customer Focus as extremely important and understands the importance of:
- Understanding of and conforming to Customer requirements
- Delivery of customer requested or required services on time

THE HSE ESTATES DEPARTMENT provide this by
- Understanding the Customer and Market requirements for our products and services
- Subsequently evaluation of our abilities to deliver those products and services on time
- Utilising the processes in place for dealing with all queries/ comments and / or complaints received.
5.2 Customer Focus

THE HSE ESTATES DEPARTMENT Quality Policy is posted in the reception area of the facility. Uncontrolled copies are made available to customer upon request. The Quality Policy is reviewed under the Quality Management Review framework. This review will provide for the following, in relation to the Quality Policy, that it remains appropriate to the purpose of the organisation, that it included a commitment to comply with the requirements and continuously improve the effectiveness of the Quality Management system, that it provides a framework for the establishment and review of the Quality Objectives, that it is communicated and understood within the organisation and it is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality Objectives

THE HSE ESTATES DEPARTMENT Management team identifies its objectives at the Management Review meeting. These are deployed to appropriate personnel within the organisation. The Quality Objectives are consistent with the Quality Policy and are reviewed for effectiveness on a regular basis. Every effort is made to ensure that objectives follow the following criteria: that they are
- Time based
- Measurable
- Achievable
- Specific
- Relevant to the assignee

Objectives include those necessary to meet the requirements of our service.

5.4.2 Quality Management system Planning

The Management Review Process is in the forum employed for evaluating current business conditions in HSE - ESTATES WEST. This consists of a review of our Quality Policy and the effectiveness of the current QMS in achieving specified goals/ objectives. See section 5.6 for further details.
5.5 Responsibility, Authority and communication

5.5.1 Responsibility and Authority

Responsibility, authority and the interrelationship among personnel are clearly defined and documented. The relevant documentation includes:

- THE HSE ESTATES DEPARTMENT organisation chart (see introduction section of the manual)
- Job descriptions that are documented for each role in the Organisation, held in HR
- Documented procedures, which communicate clearly the defined responsibilities and interrelationship of personnel

5.5.2 Management Representative

The responsibility for the Quality Management and the co-ordination of processes and instructions outlined within this manual rests with the Quality Management Representative Joe Hoare.

THE HSE ESTATES DEPARTMENT understands that employee’s involvement is key to Business success and as such quality is the responsibility of all employees of the Organisation.

The QMR is responsible for ensuring that processes for the Quality Management System is established, implemented and maintaining, and reporting on the performance of the QMS and any need for improvement that may be necessary.

The Management Representative is also responsible for coordinating all communication with the Certification Body regarding the effectiveness of the QMS.

5.5.3 Internal Communication

The team based organisational structure naturally facilitates the free flow of communication. Frequent team meetings, including weekly team meetings and Management review meetings, keep all staff informed of current issues. The QM is responsible for communication regarding the effectiveness of the QMS throughout the Organisation. Methods employed to do this include both formal (management review, memo’s, emails etc.) and informal (mentoring, coaching etc.)
5.6 Management Review

5.6.1 General

The Management at THE HSE ESTATES DEPARTMENT has agreed to meet annually to review the Quality system and to ensure its continuing suitability, adequacy and effectiveness. This review will include assessing opportunities for improvement and the need for changes to the QMS, including the Quality Policy and objectives.

The QM shall coordinate these meetings, and records will be maintained covering the items specified in 5.6.2. and 5.6.3 below:

5.6.2. Review Input

The Management Review agenda will include the following items:

- Audit Results
- Customer Feedback
- Process performance and product conformity
- Status or Corrective and Preventative action
- Follow up from earlier Management Review Meetings
- Planned changes that could affect the QMS
- Recommendations for improvement

5.6.3. Review Output

The output from the Management Review Meeting shall include and decisions and actions related to:

Improvement of the efficiency of the QMS and its processes
Improvement of the product related to customer requirements
Resource needs

See Procedure No 303 Management Review Procedure
6.2 Human Resources

6.2.1. General
All personnel performing work that affects quality will have been interviewed and selected in accordance with the qualification and/or work experience requires, as stated in the job description for that position.

6.2.2. Competence, Awareness and Training
THE HSE ESTATES DEPARTMENT has determined the necessary competences and needs for personnel performing work affecting service qualify. These are clearly visible in job descriptions, which are available for all employees in the HR department.

Where necessary, training and development will be provided to satisfying training needs (knowledge, skills, abilities or attitudes) identified. Records of all training and development initiatives are maintained, as well as all records of education, training and skills and experience. Training and development will be evaluated for effectiveness at the Management Review meeting, depending on the types of training received by individuals.

Each individual at THE HSE ESTATES DEPARTMENT is made aware of the relevance and importance of their activities and how they contribute to the achievement of the quality and Business objectives. See HSE - Human Resource Department.

6.3 Infrastructure
THE HSE ESTATES DEPARTMENT shall ensure that the infrastructure in place will be maintained at such a level to achieve conformity to Service requirements. This will apply to the following areas:

- Building, workspace and associated utilities
- Process equipment (both hardware and software)
- Supporting services (transport and communication)

See Procedures No 100 – Maintenance Section.
6.4 Work Environment

The Work Environment at THE HSE ESTATES DEPARTMENT is managed effectively to achieve conformity to service requirements. Essential elements of the work environment that are considered include lighting, heating, ventilation, noise, hygiene, humidity, cleanliness, vibration, airflow and pollution as appropriate.


7 Service Realisation

7.1. Planning of Service Realisation

THE HSE ESTATES DEPARTMENT have determined Customer requirements prior to a commitment to supply. Requirements both stated by the Customer and THE HSE ESTATES DEPARTMENT shall determine un stated but required by Legal or Regulatory reasons.

7.2.2. Review of requirements related to the service

All requirements related to the service being offered by THE HSE ESTATES DEPARTMENT are reviewed. This occurs both formally and informally. More specifically the Management Review identified and planned modifications to the service based on feedback form customers, employees providing the service and other interested parties.

7.2.3. Customer Communication

THE HSE ESTATES DEPARTMENT have a website which provides information to customers about the Organisation services. THE HSE ESTATES DEPARTMENT have dedicated staff to deal with Customer Accounts.

HSE Web Site.

7.3 Design and Development

The detailed design for capital projects are carried out off-site by approved design teams. The capital projects team in-house ensure that the design is carried out in a controlled manner. All stages are subject to review and approval by the HSE prior to proceeding to the next stage.

Construction work is also outsourced. It is the responsibility of the Estates to ensure that this work is procured, approved and managed in a controlled manner.

Service agreements are in place for some of the equipment particularly biomedical in our hospitals. Procurement, award and management of these contracts are controlled by the Estates Department in line with the quality procedures.

Refer to sections of the Quality Procedures Manual including capital projects. Maintenance, Fire Safety and Corporate Management function.
7.4 Purchasing

THE HSE ESTATES DEPARTMENT are carried out inline with public procurement guidelines and EU Directives. Supplies and services are only purchased for an approved supplier. Issues with supplier or sub contractors are logged on the C/PAR log and followed up to completion.

7.4.2 Purchasing Information

Purchase orders are raised for all purchases in HSE - ESTATES WEST. The Purchase Order is approved prior to issue to the Supplier or Sub contractor.

Design team selection will be accepted subject to minimum relevant qualifications

7.4.3 Verification of purchased product

Purchased product is checked against the raised order on receipt. IF acceptable the delivery docket is signed as confirmation of receipt. Any discrepancies (that prevent use of the purchased items) identified shall be documented and details communicated to the Supplier. See Public Procurement Procedures and EU Directives.

7.5 Production and Service Provisions

7.5.1 Control of Production and Service Provision

Service provision is planned and carried out refer to Procedures No 10 series – Capital Projects Section, Procedures No 100 series – Maintenance Section Procedures, No 200 series – Fire Safety Section, Procedures No 400 series – Corporate Management Section Procedures No 500 series – Fire Safety Section. Informal meetings also take place where:

- Existing Contracts are reviewed
- New Jobs are discussed
- Any other Business discussed

Complaints/ comments/ Feedback, Management Review and internal Audits are also used as a source of information to identify areas for improvement with respect to the planning and control of service provision. Refer to appropriate procedures. (see Master Document List)

7.5.2 Validation of processes for production and service provision

This Clause is not applicable to HSE - ESTATES WEST.

7.5.3 Identification and Traceability

All service jobs are identified by number and/or title. This number and/or title is used to trace all communication and documentation relating to a job.

7.5.4 Customer Property
Documentation taken from the Customer is maintained in good condition. Any damage to customer Property is noted to the Customer and documented by the Organisation. All customer information is considered confidential with employees of the department and it is not divulged outside of the department.

7.5.5 Preservation of Product

The server takes a backup of all files and systems on a daily basis to ensure that all computer files are preserved. Virus software is installed on the network and runs automatically. The virus software ensures that systems remain free from virus.

7.6 Calibration

Inspection, Measuring and Test Equipment is selected for each process to meet process requirements, maintained in good working order and stores in suitable environmental conditions. Calibration is carried out where necessary on key items. Refer to Calibration Records held by the relevant officer. Each item of inspection, measuring and test equipment requiring calibration is identified with its calibration status and reference to relevant international Standard and indicates the next calibration date. Any equipment found to be out of calibration will be removed from use.
8 Measurement, analysis and improvement

In THE HSE ESTATES DEPARTMENT we understand the importance of measurement and that it is through measurement that improvements can ultimately be verified.

Areas of particular interest to THE HSE ESTATES DEPARTMENT include:
- Conformance of the product/service
- Conformity of the QMS and
- Continual improvement and effectiveness of the QMS

8.2 Monitoring and Measurement

8.2.1. Customer Satisfaction

In THE HSE ESTATES DEPARTMENT has a number of methods are employed for identifying, documenting and resolving customer Satisfaction issues. The tools employed include:
- Customer complaints
- Direct Customer Communication with customers and other interested parties
- Questionnaires and surveys
- Sector studies
- Reports from customer Organisations

Measurement and Feedback

Trends in Customer Satisfaction and key indicators of customer Dissatisfaction shall be discussed prior to the Management Review meeting. Such indicators shall be supported by objective information.

Where appropriate these trends will be compared to those of similar service providers or other appropriate benchmarks, and reviewed by the Management Team.

See Procedure No 307 Customer Feedback Procedure

8.2.2. Internal Audit

A Comprehensive audit programme is in place to ensure that all processes, procedures and departments that fall under the Quality Management system are audited at least annually. The Quality Representative will determine how often the processes needs to be audited depending on the status and importance of each activity.

Internal auditors are training at a minimum to internal Auditor level. Where practicable, auditors assigned to audit a specific procedures/processes/areas will be independent of the area being audited. Audit findings/coercive actions and follow up are competed through the corrective action process.
Refer to internal Audit Procedure number 305 for further details.

8.2.3. Monitoring and Measurement of processes

THE HSE ESTATES DEPARTMENT shall employ the Quality Management Review Meeting as a method for monitoring and measurement of the Organisation's QMS and its processes. The Management Review shall provide the platform by which the Quality objectives shall be reviewed and their achievement measured.

Corrective and Preventative action shall be taken as required.

8.2.4. Monitoring and Measurement of product

THE HSE ESTATES DEPARTMENT measure and monitor its services on a day to day basis, refer to Master Document List for Details.

8.3 Control of non-conforming product

THE HSE ESTATES DEPARTMENT ensures the elements of the service, which do not conform to service requirements, are identified and controlled. The controls and related responsibilities and authorities for dealing with nonconforming product are detailed in procedure No 303.

Typical examples of non-conforming procedure include:
- Work schedules not adhered to
- Customer queries not followed up on
- Customer requirements not addressed

THE HSE ESTATES DEPARTMENT will deal with nonconforming product by identifying and eliminating the root cause.

Record of the non-conformity and any subsequent action taken are maintained and documented.

8.4 Analysis of Data

THE HSE ESTATES DEPARTMENT collects data to enable decisions to be made in order to effect the continual improvement of its services.
Data obtained through analysis, along with that data as obtained through the Management Review, Customer Feedback, Conformity to service, legal and regulatory requirements, Corrective and Preventive action shall be used to make such decisions and take such action as deemed necessary to promote the idea of continual improvement and the achievement of the organisation goals and objectives.

The results of analysis are used to determine trends, operational performance, customer satisfaction and dissatisfaction, satisfaction levels of other interested parties, effectiveness and efficiency of the organisation and its processes, supplier contribution, financial related performance and also benchmarking of performance as appropriate.

8.5 Improvement

8.5.1. Continual Improvement

THE HSE ESTATES DEPARTMENT will continually seek to improve the effectiveness and efficiency of the processes of the organisation, rather than waiting for a problem to reveal opportunities for improvement.

Continual Improvement is monitored at the Management Review Meeting.

See Procedure No 303 Management Review Procedure

8.5.2. Corrective Actions

Corrective actions will be used as a tool in continual improvement. They will be used to identify the root cause of nonconformities and ensure that avoidance of the issue reoccurring.

Staff from relevant disciplines will participate in the corrective action process.
Corrective action can be raised for a number of reasons and relating to many issues but will include both process nonconformities and service non-conformities.

The effectiveness and efficiency of processes shall be emphasised when actions are taken and those actions shall be monitored to ensure the desired goals are achieved.

To avoid misuse and inconsistency of the corrective action process, the Quality Manager reviews all corrective action before they are logged. The Quality Manager has the responsibility of logging it onto the system.

All corrective actions raised will be incorporated for discussion in the Management review meeting.

Refer to procedure no 304 Corrective and Preventative Action for more details.
8.5.3. Preventative Actions

THE HSE ESTATES DEPARTMENT Management Team recognise the need for planning in order to reduce the effects of loss to THE HSE ESTATES DEPARTMENT (i.e. litigation risk and risk management, in general) and also to maintain the performance of processes and products.

Data will be collected and analyses based on appropriate methodology, including historical data. This data may be generated with the use of risk analysis tools such as failure mode and effect analysis and investigation of risk, review of customers needs and expectations, customer feedback and/or satisfaction, relevant Quality system management records and processes that provide early warning of approaching out of control operating conditions.

Such data will provide information that will allow Management Team to identify and prevent any issue from arising that would if unchecked impact on the services, customers needs and expectation and the efficiency and effectiveness of the operations.

Refer to procedure no 304 Corrective and Preventative Action for more details.
Refer to procedure no 303 Management Review Procedure.
Refer to Health and Safety Manual.
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<td>Added appendix d interaction between the processes</td>
<td>13th September 07</td>
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<tr>
<td>All</td>
<td>L.Naughton</td>
<td>Reference to Technical Services, ISO 9001:2000</td>
<td>9th April 09</td>
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APPENDIX B: QUALITY POLICY

The Estates Department is a Department of the HSE West Area that is responsible for providing expert advice and support in relation to technical issues, including estate management, energy management, fire safety, technical training compliance auditing, quality assurance, value for money, and standard setting so as to ensure effective implementation of policy and legislation and to manage selected projects in consultation with line management.

Business Objectives are:

- To ensure a safe and well maintained environment and infrastructure for Patients and staff
- To liaise with service procedures in managing and prioritizing capital investment programmes for minor and Major capital projects

Each year the objectives are reviewed. Programmes are developed in line with the business Objectives.

The Management and staff of the Organisation aim to:

- Provide a service, which continually meet the agreed requirements and expectations of our clients.
- Allocate sufficient and appropriate resources to establish and maintain a Quality Management System to achieve and retain ISO 9001 Certification.
- Continually improve the effectiveness of the Quality Management System

The Quality Assurance System is in line with the requirements of EN ISO 9001 2008.

Date of Issue: _________________   Approved By: _________________  
Joe Hoare.

Appendix C: Organisation Chart.
Appendix D: Interaction Between the processes