Patient Transport UK Ltd

Professional, Reliable, Personal

Business Management System

ISO 9001:2015

ISO 14001: 2015

(Integrated)

Patient Transport UK Ltd

Professional, Reliable, Personal

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ISO 9001:2015 & ISO14001:2015 Control Document

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1. INTRODUCTION

This document is the Business Management Manual (the Manual) of Patient Transport (UK) Ltd and for the purpose of this manual will be referred to as 'PTUK'.

The Manual is the property of PTUK and is a controlled document.

The purpose of the Manual is to provide an overview of PTUK, the activities it carries out and the quality standards of operation it conforms to.

It is not designed to act as a procedures manual, although it does carry information about where procedures information is located and the detailed information on documentation requirements for the procedures required by the respective standards.

This Manual is designed to meet the requirements of ISO9001:2015 and any standard which adopts the Annex SL structure

1.1 THE ISSUE STATUS

The issue status is indicated by the version number in the footer of this document. It identifies the issue status of this Manual.

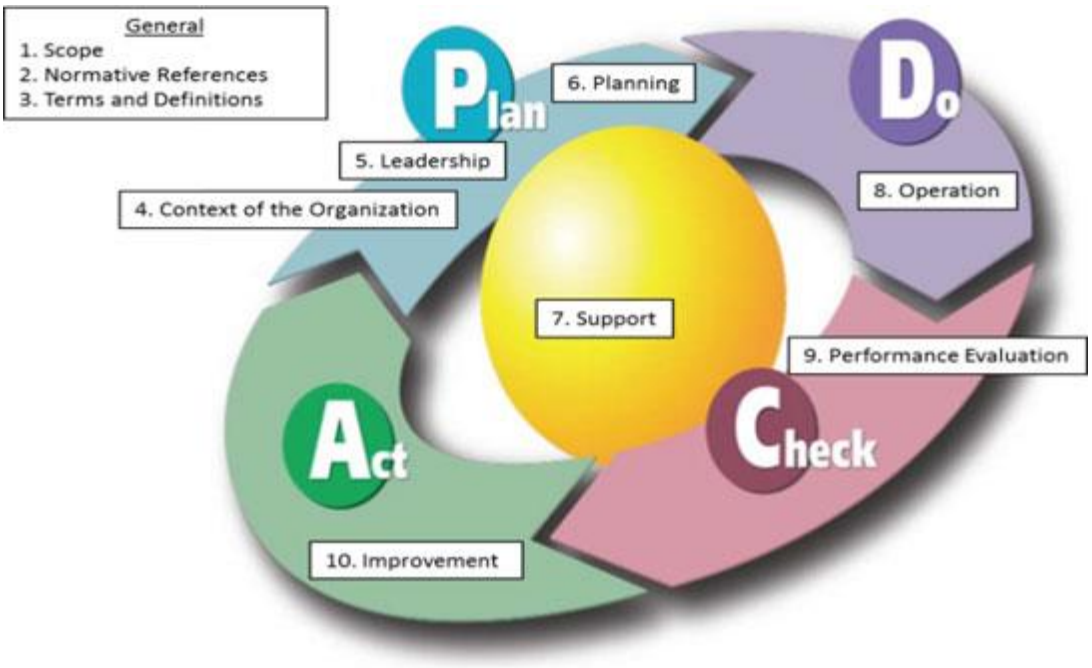
When any part of this Manual is amended, a record is made in the Amendment Log shown below.

The Manual can be fully revised and re-issued at the discretion of the Management Team.

Please note that this Manual is only valid on day of printing.

Issue	Issue Date	Additions/Alterations	Initials
1.0	01.09.2017	Business Management Manual First Authorised Issue	B.W

1.2 PLAN-DO-CHECK-ACT Model for ISO 9001:2015



1.3 QUALITY & ENVIRONMENTAL POLICY

It is the policy of PTUK to maintain a quality system designed to meet the requirements of ISO 9001:2015 & ISO14001:2015 (or any other standard in line with Annex SL Structure) in pursuit of its primary objectives, the purpose and the context of the organisation.

It is the policy of PTUK to:

- give satisfaction to all of our customers and other stakeholders and interested parties whenever possible, meeting and exceeding their expectations;
- comply with all legal requirements, codes of practice and all other requirements applicable to our activities;
- the reduction of hazards, prevention of injury, ill health, protection of the environment including prevention of pollution, sustainable resource use, climate change mitigation and adaption, the protection of biodiversity and ecosystems and any other specific commitments which are relevant to the context of the organisation;
- provide all the resources of equipment, trained and competent staff and any other requirements to enable these objectives to be met;
- ensure that all employees are made aware of their individual obligations in respect of this quality & environmental policy;
- Maintain a management system that will achieve these objectives and seek continual improvement in the effectiveness and performance of our management system based on “risk”.

This quality & environmental policy provides a framework for setting, monitoring, reviewing and achieving our objectives, programmes and targets.

Customer service is an essential part of the quality & environmental process and to ensure this is fulfilled, all employees receive training to ensure awareness and understanding of quality and environment and its impact on customer service.

To ensure the company maintains its awareness for continuous improvement, the quality & environmental system is regularly reviewed by “The Quality Management Team” to ensure it remains appropriate and suitable to our business. The Quality & Environmental System is subject to both internal and external annual audits.

Quality & Environmental Management Team

Managing Director
Operations Manager
Training Manager

2. OVERVIEW OF THE ORGANISATION

Patient Transport (UK) Limited**,** established in 2007, provide Patient Transport Services to the Healthcare industry.

We are an independent Ambulance provider based in North West London. We are a long established company with many years of experience. We have a range of Ambulances all with their specialist role.

As a company we are able to provide a range of services:

- Repatriation
- Patient Transport Services
- A&E Support Ambulance
- Bariatric Services
- Event Services

Patient Transport (UK) Ltd provides a service to our clients unrivalled in its field. Our emphasis on customer service has ensured that our clients continue to use our patient transport service. Whether you are a Private Patient, Private Hospital, Insurance Repatriation Company, Mental Health Unit, you will always be greeted by a professional trained member of staff that can guide you on the correct solution for your patient.

2.1 SCOPE OF REGISTRATION

Provision of Patient Transport services

3. QUALITY & ENVIRONMENTAL OBJECTIVES

We aim to provide a professional and ethical service to our clients. In order to demonstrate our intentions, Our Management Team will analyse customer feedback data, internal performance data, financial performance data and business performance data to ensure that our Quality Objectives are being met.

We have identified the following Quality and Environmental Objectives in accordance with SMART (Specific, Measurable, Achievable, Realistic and Timed)

- We will always endeavour to deliver our services to specification, on time and to the price quoted

  This is measured by

  - Journey Data Analysis
  - Customer Feedback
  - Staff Feedback
  - KPI Data
  - Financial Data

- We will always conduct our business in an ethical and professional manner

  This is measured by

  - Customer Feedback
  - Compliments and Complaints
  - Management Review
  - Internal Audits

- We will always endeavour to satisfy our clients' requirements and get things right first time. Should we make a mistake, we will admit it and rectify the situation as quickly as possible.

  This is measured by

  - Non-conformances
  - Complaints
  - corrective action reports
  - customer feedback
  - KPI Data
  - Internal Audit

- We will comply with all compliance obligations, codes of practice and all other requirements applicable to our activities including the nature, scale and environmental impacts of it's activities, products and services.

  This is measured by

  - Non-conformances
  - Complaints
  - corrective action reports
  - customer feedback
  - KPI Data

- Internal Audit

- We will ensure that the reduction of hazards, prevention of injury, ill health, protection of the environment, including prevention of pollution, sustainable resource use, climate change mitigation and adaption, the protection of biodiversity and ecosystems are measured and acted upon accordingly.

This is measured by

- Non-conformances
- Complaints
- corrective action reports
- customer feedback
- KPI Data
- Internal Audit

4. CONTEXT OF THE ORGANISATION

4.1 Understanding the organisation and its context

The context of the organisation is demonstrated within this Business Management System and all associated processes connected with the services / products offered.

Legal and Regulatory Legislation	Hyperlink
Bribery Act 2010	http://www.legislation.gov.uk/ukpga/2010/23/contents
Care Act 2014	http://www.legislation.gov.uk/ukpga/2014/23/contents/enacted
Care And Quality Commission	http://www.cqc.org.uk/
Care Standards Act 2000	http://www.legislation.gov.uk/ukpga/2014/23/contents/enacted
Children And Families Act 2014	http://www.legislation.gov.uk/ukpga/2014/6/contents/enacted
Children's Act 2004	http://www.legislation.gov.uk/ukpga/2004/31/contents
Clean Air Act 1993 (Smoke Control)	http://www.legislation.gov.uk/ukpga/1993/11/contents
Clean Neighbourhoods and Environment Act 2005	http://www.legislation.gov.uk/ukpga/2005/16/contents
Clean Neighbourhoods and Environment Act 2005 Parts III and V	http://www.legislation.gov.uk/ukpga/2005/16/contents
Computer Misuse Act 1990	http://www.legislation.gov.uk/ukpga/1990/18
Consumer Protection Act 1987	http://www.legislation.gov.uk/ukpga/1987/43
Control of COSHH Regulations 2002	http://www.hse.gov.uk/coshh/detail/coshh-clp-reach.htm
Control of Pollution Act 1974	http://www.legislation.gov.uk/ukpga/1989/14/contents
Control of Pollution Act 1974 Sections 60 and 61	http://www.legislation.gov.uk/ukpga/1989/14/contents
Control Of Substances Hazardous To Health Regulations 2002	http://www.hse.gov.uk/coshh/detail/coshh-clp-reach.htm
Controlled Waste (Amendment) Regulations 1993 (SI 1993/566)	https://www.gov.uk/guidance/waste-legislation-and-regulations
Data Protection Act 1998	https://www.gov.uk/data-protection/the-data-protection-act
Deprivation Of Liberty Safeguards 2005	https://www.lawsociety.org.uk/support-services/advice/articles/deprivation-of-liberty/
Disability Discrimination Act 1995	http://www.legislation.gov.uk/ukpga/1995/50/contents
Disclosure And Barring Service	https://www.gov.uk/government/organisations/disclosure-and-barring-service/about
Employers' Liability (Compulsory Insurance) Act 1969	http://www.legislation.gov.uk/ukpga/1969/57/section/2
Employment Act 2002	http://www.legislation.gov.uk/ukpga/2002/22/contents
Energy Information (labelling) Regulations	https://www.gov.uk/guidance/the-energy-labelling-of-products
Energy Performance of Buildings (Certificates and Inspections) (England and Wales) Regulations 2007 SI 991	https://www.gov.uk/guidance/energy-performance-of-buildings-certificates-notes-and-definitions
Environmental Protection (Controls on Ozone-Depleting Substances) Regulations 2002 (SI 2002/528)	http://www.legislation.gov.uk/uksi/2002/528/contents/made
Environmental Protection (Duty of Care) Regulations 1991	http://www.legislation.gov.uk/uksi/2002/528/contents/made

Environmental Protection Act 1990	http://www.legislation.gov.uk/ukpga/1990/43/contents
Environmental Protection Act 1990 (as amended by the Noise and Statutory Nuisance Act 1993 & the Environment Act 1995) Part III	http://www.legislation.gov.uk/ukpga/1990/43/contents
Environmental Protection Act 1990, Part II	http://www.legislation.gov.uk/ukpga/1990/43/contents
Environmental Protection Act 1990, Part III	http://www.legislation.gov.uk/ukpga/1990/43/contents
Environmental Protection Act 1990, Part III (Statutory Nuisance)	http://www.legislation.gov.uk/ukpga/1990/43/contents
Equality Act 2010	https://www.gov.uk/guidance/equality-act-2010-guidance
EU Regulation on Detergents; The Detergents Regulations 2005, SI 2469	http://www.legislation.gov.uk/id/uksi/2005/2469
Finance Act 1996	http://www.legislation.gov.uk/ukpga/1996/8/part/III
Finance Act 2016	http://www.legislation.gov.uk/ukpga/2016/24/pdfs/ukpga_20160024_en.pdf
Freedom of Information Act 2000	http://www.legislation.gov.uk/ukpga/2000/36/contents
Hazardous Waste (England and Wales) Regulations 2005 (SI 2005/894)	http://www.legislation.gov.uk/uksi/2005/894/pdfs/uksi_20050894_en.pdf
Health And Safety (First Aid) Regulations 1981	http://www.hse.gov.uk/firstaid/legislation.htm
Health And Safety (Sharp Instruments In Healthcare) Regulations 2013	http://www.hse.gov.uk/pubns/hsis7.htm
Health and Safety at Work etc. Act 1974	http://www.hse.gov.uk/legislation/hswa.htm
Human Rights Act 1998	http://www.legislation.gov.uk/ukpga/1998/42/contents
Lifting Operations And Lifting Equipment Regulations 1998	http://www.hse.gov.uk/pubns/indg290.pdf
Management Of The Health And Safety At Work Regulations 1999	http://www.legislation.gov.uk/uksi/1999/3242/regulation/3/made
Manual Handling Operations Regulations 1992	http://www.hse.gov.uk/msd/pushpull/regulations.htm
Mental Capacity Act 2005	http://www.legislation.gov.uk/ukpga/2005/9/contents
Noise and Statutory Nuisance Act, 1993	http://www.legislation.gov.uk/ukpga/1993/40/contents
Noise at Work Regulations 1989	http://www.hse.gov.uk/NOISE/REGULATIONS.HTM
Offices, Shops and Railway Premises Act 1963	http://www.legislation.gov.uk/ukpga/1963/41/contents
Pension Schemes Act 2015	https://www.gov.uk/government/collections/pension-schemes-bill-2014-to-2015
Pollution Prevention and Control (England and Wales) (Amendment) Regulations 2002, SI 2002/275.	http://www.legislation.gov.uk/ukpga/1999/24/introduction
Pollution Prevention and Control (England and Wales) (Amendment) (No 2) Regulations 2002, SI 2002/1702.	http://www.legislation.gov.uk/ukpga/1999/24/introduction
Pollution Prevention and Control (England and Wales) (Amendment)	http://www.legislation.gov.uk/ukpga/1999/24/introduction

Regulations 2003, SI 2003/1699.	
Pollution Prevention and Control (England and Wales) (Amendment) Regulations 2007	http://www.legislation.gov.uk/ukpga/1999/24/introduction
Pollution Prevention and Control (England and Wales) Regulations 2000 (SI 2000/1973)	http://www.legislation.gov.uk/ukpga/1999/24/introduction
Pollution Prevention and Control (England and Wales) Regulations 2000, SI 2000/1973.	http://www.legislation.gov.uk/ukpga/1999/24/introduction
Pollution Prevention and Control Act 1999	http://www.legislation.gov.uk/ukpga/1999/24/introduction
Provision And Use Of Work Equipment Regulations 1998	http://www.hse.gov.uk/work-equipment-machinery/puwer.htm
Public Disclosure Act 1998	http://www.legislation.gov.uk/ukpga/1998/23/contents/enacted
Regulation on Substances that Deplete the Ozone Layer (EC/2037/2000)	https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/394831/fgas-gen2-fluid-uses.pdf
Regulatory Reform (Fire Safety) Order 2005	http://www.hse.gov.uk/toolbox/fire.htm
Reporting Of Injuries, Diseases, And Dangerous Occurrences Regulations 2013	http://www.hse.gov.uk/riddor/
Social Security Administration Act 1992	http://www.legislation.gov.uk/ukpga/1992/5/pdfs/ukpga_19920005_290216_en.pdf
The Health and Safety (Display Screen Equipment) Regulations 1992	http://www.hse.gov.uk/msd/dse/
The Lifting Operations and Lifting Equipment Regulations 1998	http://www.hse.gov.uk/work-equipment-machinery/loler.htm
The Manual Handling Operations Regulations 1992	http://www.hse.gov.uk/msd/pushpull/regulations.htm
The Noise Act 1996 (The Act is amended by the London Local Authorities Act 2007)	http://www.legislation.gov.uk/ukpga/1996/37/pdfs/ukpga_19960037_en.pdf
The Personal Protective Equipment at Work Regulations 1998	http://www.hse.gov.uk/toolbox/ppe.htm
The Provision and Use of Work Equipment Regulations 1998	http://www.hse.gov.uk/work-equipment-machinery/puwer.htm
The Public Passenger Vehicles Act 1981.	http://legislation.data.gov.uk/ukpga/1981/14/contents/data.htm?wrap=true
The Regulatory Reform (Fire Safety) Order 2005	http://www.hse.gov.uk/toolbox/fire.htm
The Road Traffic Act 1972.	http://www.uklaws.org/statutory/instruments_02/doc02136.htm
The Road Traffic Regulation Act 1984	http://www.legislation.gov.uk/ukpga/1984/27/contents
The Road Vehicles (Construction and Use) Regulations 2007	http://www.hse.gov.uk/workplacetransport/legislation.htm
The Road Vehicles Lighting Regulations 1989	http://www.legislation.gov.uk/uksi/1989/1796/contents/made
The Supply of Machinery (Safety) Regulations 2008	http://www.legislation.gov.uk/uksi/2008/1597/contents/made
The Vehicles (Excise) Act 1971	http://www.legislation.gov.uk/ukpga/1971/10/enacted
The Waste (England and Wales)	http://www.legislation.gov.uk/ukdsi/2011/9780111506462/contents

Regulations 2011	
The Workplace (Health, Safety and Welfare) Regulations 1992	http://www.hse.gov.uk/pubns/books/l24.htm
Waste Electrical and Electronic Equipment Regulations 2013	http://www.legislation.gov.uk/uksi/2012/632/contents/made
Waste Management (Miscellaneous Provisions) (England and Wales) Regulations 2007 SI 1156	http://www.legislation.gov.uk/uksi/2007/1156/contents/made
Waste Management Licensing (Amendment) (England) Regulations 2003 (SI 2003/595)	http://www.legislation.gov.uk/uksi/2003/595/contents/made
Work At Height Regulations 2005	http://www.hse.gov.uk/work-at-height/the-law.htm

PTUK evaluate legal compliance using policy documentation and regular review of legislation against standards and service. These reviews are conducted during management review meetings and internal audits by the Senior Management Team.

4.2 Understanding the needs and expectation of interested parties

Interested Parties	Information Requirements
Directors	• To ensure that the business continues to function without hindrance and bureaucracy. • To ensure business information is kept confidential, available and reliable.
Managers	• To protect client confidentiality • To ensure employment processes are followed. • To ensure Information Security training has been carried out. • To ensure all relevant HR documentation is up to date
Employees	• To protect client confidentiality • To ensure employment processes are followed. • To ensure Information Security Policies/Procedures are followed. • To take responsibility for their own training
Contractors	• To ensure all related information is kept confidential • Meet the requirements of the Data Protection Act 1998 • To ensure integrity of the systems are maintained as appropriate • To ensure adherence to relevant SLAs
Suppliers	• To ensure all related information is kept confidential • Meet the requirements of the Data Protection Act 1998 • To ensure integrity of the systems are maintained as appropriate • To ensure adherence to relevant SLAs
Accountants	• To ensure all related information is kept confidential

	• Meet the requirements of the Data Protection Act 1998
Company Solicitors / Lawyers	• To protect client confidentially. • To ensure that clients requests are adhered to all at times.
Governing Bodies	• To ensure correct process and procedure. • To ensure that services are delivered in a safe and appropriate manner.
Regulatory Bodies	• To conduct inspection based on service requirements. • To generate report and ratings based on inspection outcomes.
Neighbouring Business (Environmental)	• To manage environmental aspects in line with legislation • To ensure all processes have been assessed for environmental impact
Landowners (Environmental)	• To manage environmental aspects in line with legislation • To ensure all use of land is environmentally sustainable

4.3 Determining the scope of the quality management system

Determine the boundaries and applicability of the quality management system to establish its scope taking into account internal / external issues and the interested parties. This would also include the products and services of the organisation.

- All legal requirements are encompassed in our scope as indicated in 4.1
- The terms of the scope in the Quality and Environmental Management System covers all information in 4.2
- All internal and external issues are detailed in Doc008 - Possible Internal and External Issues.docx

4.4 Part 1 - Quality Management system and its processes

PTUK is responsible for the planning and delivery of its services. We work closely with our partner suppliers and customers to satisfy mutual requirements. We have a flow chart of illustrate the interaction of our core business processes, as shown below:

Stage 1 – Initial Enquiry (Control Team)

- Client Phones or emails the office
- Crew/vehicle availability confirmed
- Assess crew/vehicle/resources required
- Booking form completed/received
- Price quotation sent to client
- Quote accepted by client
- Acceptance of journey confirmed

Stage 2 – Programme & Planning (Control Team)

- Location of available crews checked
- Journey allocated to crew
- Crew confirm receipt of journey details
- Crew check vehicle is fully equipped, stocked, and fuelled
- Crew assess route to collection address prior to travel

Stage 6 – Purchasing (Finance Manager)

- Requirement Identified
- Purchase Request Completed
- Request Confirmed
- Purchase made
- Stock Delivered
- Delivery Note and Receipt Processed

Training and Development (Training Manager)

- Induction training upon commencement of employment
- Mandatory training for all duties expected of the employee
- Driving assessment
- Field assessment (shadowing experienced staff member)
- Sign off as ready for duties
- Continuous Professional Development
- Identify any specialist training required?
- Yearly refresher training
- Any other ad-hoc training

Stage 3 – Delivery of Service (Control Team)

- Crew arrive at collection address
- Contact made with client
- Crew assess accessibility
- Crew electronically confirm arrival and collection times
- Travel to drop off destination
- Crew confirm arrival time and handover time (where applicable)
- Crew clean any equipment used
- Availability of vehicle for next journey is confirmed

Stage 4 - Feedback/Complaints (Operations Manager)

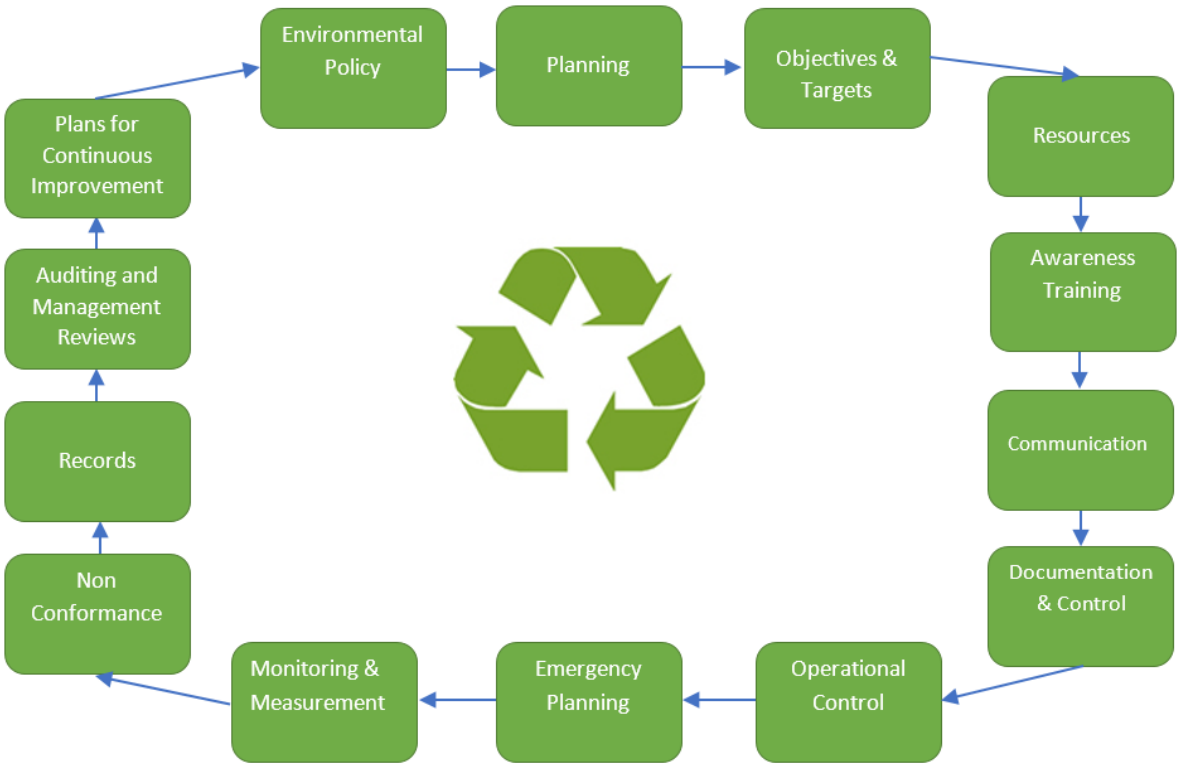
- Positive feedback relayed to crew
- Negative feedback/complaints investigated
- Crew to record their account on an incident form if there is a complaint
- Any extra training needs identified
- Instigate disciplinary procedures if there is a misconduct issue

Stage 7 – Invoicing/Credit Control (Finance Manager)

- Final Journey Data Collated
- Invoice Generated
- Invoice sent
- Invoice tracked for payment
- Invoice payment made

4.4 Part 2 - Quality Management system and its processes

PTUK is responsible for the planning and delivery of its services. We work closely with our partner suppliers and customers to satisfy mutual requirements. We have a flow chart of illustrate the interaction of our core business processes, as shown below:



5 LEADERSHIP

5.1 Leadership & Commitment

PTUK's Management Team are committed to the development and implementation of a Quality and Environmental Policy and the Quality and Environmental Management System which are both compatible with the strategic direction and the context of the organisation, the whole system is frequently reviewed to ensure conformance to the standard. Responsibility has been assigned to ensure that the QMS & EMS conforms to the requirements of the respective standard and the provision to report on performance to the Quality Management Team has been defined.

The designated senior Management Representative(s) will ensure that PTUK staff are aware of the importance of meeting customer as well as statutory and regulatory requirements, and overall, to contribute to achieving PTUK's Quality and Environmental Policy and Objectives which are aligned with the current business plan.

The Senior Management Team is responsible for implementing the QMS and ensuring the system is understood and complied with at all levels of the organisation.

In summary, the Senior Management Team will ensure that:

5.1.1 Leadership and commitment for the quality management system

- The company has a designated Quality and Environmental Management Team who is responsible for the maintenance and review of the Quality and Environmental Management Systems.
- The ongoing activities of PTUK are reviewed regularly and that any required corrective action is adequately implemented and reviewed to establish an effective preventative process.
- Measurement of our performance against our declared Quality and Environmental Objectives is undertaken.
- Resources needed for the BMS are available and employees have the necessary training, skills and equipment to effectively carry out their work.
- Internal audits are conducted regularly to review progress and assist in the improvement of processes and procedures.
- Objectives are reviewed and, if necessary amended, at regular Review meetings and the performance communicated to all staff.
- The BMS is integrated into the organisations business processes.
- Communication covering the importance of the effective BMS and conformance to the BMS requirements is in place.
- Continual improvement is promoted.
- The contribution of persons involved in the effectiveness of the BMS is achieved by engaging, directing and supporting persons and other management roles within their area of responsibility.

5.1.2 Customer Focus

- Customer requirements and applicable statutory and regulatory reuirements are determined and met
- The risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed
- The focus on consistently providing products and services that meet customer and applicable statutory and regulatory requirements is maintained
- The focus on enhancing customer satisaction is maintained

5.2 Quality/Environmental Policy

The Quality Policy of PTUK is located within section 1.3 of this Manual – Quality/Environmental Policy.

5.3 Organisational roles, responsibilities and authorities

PTUK has an organisation chart in place as well as employee contracts together with job descriptions to ensure that the appropriate personnel are in place to cover the whole context of the organisation and strategy of the business.

Please see below document:-
Doc002 - Organisation Chart.docx

6 Planning for the Business Management System

6.1 Actions to address risk and opportunities

We have identified the following process as a means of identifying and determining the risks and opportunities that are relevant to our Business Management system. The Risk & Opportunities document is separate to this manual.

Within each of the areas the risks (if any) are identified together with a rating as to the importance of the risk. The associated consequence, severity & mitigation of the risk is also noted together with the probable likelihood of the risk occurring.

We use an Excel spreadsheet to collect and analyse the risks and opportunities

The Risk and opportunities document is reviewed frequently by the Senior Management Team to ensure the effectiveness of the actions have been fulfilled.

Please see below document:-
Doc005 - Risk Management & Opportunities (QMS).xlsx

6.1.2 Environmental Aspects

PTUK has conducted a review based on change (which includes planning and new developments), new or modified activities, products or services to identify and evaluate aspects, impacts and risk connected to its business operation. These include people, activities, buildings, services and the scope of the Business Management System.

The review of the environmental aspects is undertaken by the Senior Management Team at regular intervals to ensure they are valid.

Please see below document:-
Doc058 - Aspects & Impacts Register

6.1.3 Compliance Obligations

PTUK has determined compliance obligations which are connected to the operation of our business and is contained within the Aspects & Impacts Register on a separate tab. The related document is reviewed by Top Management at regular intervals.

Please see below document:-
Doc052 - Compliance Obligations

6.1.4 Planning Action

PTUK takes actions to address significant environmental aspects, compliance obligations and risk and opportunities in the following documents:-

Please see below documents
Doc058 - Aspects & Impacts Register
Doc052 - Compliance Obligations
Doc005 - Risk Management & Opportunities (QMS).xlsx

6.2.1 Quality/Environmental Objectives and planning to achieve them

The Quality Objectives and methods of achieving the objectives is located within section 3 of this Manual – Quality Objectives.

The Senior Management Team will determine environmental objectives and targets based on the identified significant aspects. This will be carried out initially and then repeated as part of our management review.

Objectives and targets will be measurable where possible and will be consistent with our commitment to prevent pollution, our commitment to comply with compliance obligations as necessary and to ensure we achieve continuos improvement.

When determining objectives and targets, considerations will include, technological options, financial, operational and business requirements together with the views of interested parties.

On completion of determining the objectives and targets they will be recorded in our matrix and will then be used to develop the programme for implementing actions designed to ensure the individual targets are met and the overall objectives achieved.

6.2.2 Planning actions to achieve environmental objectives

The Senior Management Team regularly review environmental objectives, which are contained within our objectives policy together with our aspects & impacts register.

6.3 Planning of Changes (Quality)

The Senior Management Team of PTUK identify any potential changes, this is then delegated to a responsible person as a “project manager”.

He or she will conduct a “research background” to determine the feasibility of the changes with regards to:-

- Purpose of the change
- Any potential consequences
- Integration of the quality management system
- The availability of resources
- The allocation or reallocation of responsibilities and authorities
- Technical Skills
- Timescales
- Risks
- Impact

Please see below document:-
Doc006 - Planning of Changes.docx

7 Support

7.1 Resources

7.1.1 General

PTUK determines and provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

We ensure that the below elements are taken into account when completing an evaluation:

- The capabilities of, and constraints on, existing internal resources;
- What needs to be obtain from external providers

7.1.2 People (Quality)

Operation and context of the organisation is taken into account when we determine the relevant persons necessary for the effective operation of the quality management system.

7.1.3 Infrastructure (Quality)

All of our administration is conducted at our Head Office. This includes:-

- Management of financial matters
- Handling of client orders
- Personnel records

In terms of equipment used to deliver our product / service, asset registers and maintenance records are kept for the following:

- Office Space (enter the size)
- Utilities
- Hardware / software
- Technology
- Machinery (list)
- Vehicles
- Plant equipment
  Etc…

Please see below link to company Asset Register

Doc004 - Asset Register.xlsx

7.1.4 Environment for the operation of processes (Quality)

The PTUK environment consists of 2 3800 square foot areas (Units) with car parking, storage, office space and washroom facilities. Temperature controls are in place and also HVAC systems. All equipment is maintained. The office space consists of 5 people whom all have undergone DSE evaluation and appropriate equipment is in place to alleviate any restraints on the employee. There are no psychological factors to take into consideration / we monitor our employees through appraisals and general meeting for their wellbeing which includes stress. Cleanliness is very good with sub-contract cleaners visiting the site once per week. The ergonomic layout is very good minimising any impacts to the environment. Waste is specifically managed to allow optimum recycling and energy efficient appliances are used where possible. Lighting is managed to reduce unnecessary energy use.

7.1.5 Monitoring and measuring resources (Quality)

We ensure that all relevant equipment and personnel are monitored and measured to ensure that equipment and personnel are effective for the services / products we offer:-

Equipment: We ensure that all equipment is serviced, maintained and where applicable calibrated to statutory and regulatory requirements (see documented evidence within our maintenance, service and calibration records).

Personnel: We ensure that all personnel are monitored on a regular basis (please see personnel records for training etc). We maintain a monitoring / training matrix as evidence. Please see link to training matrix below.

Doc019 - Staff Matrix

7.1.6 Organisation Knowledge (Quality)

We ensure that "Job Specifications" are produced which include knowledge requirements for each individual role. Specific tests are implemented to ensure that persons are knowledgeable with the specific elements of the role. This could include telephone interview, tests, internal training or vocational certificates.

7.2 Competence

All employees have the training and skills needed to meet their job requirements. All employees are monitored on an ongoing basis to identify any training and development needs. Competences and training needs are identified / satisfied by using:

Please see below "hyperlinked documentation as demonstration of compliance:

- Job descriptions which set out the competences required
- Contracts of employment which set out contractual and legal requirements
- Induction checklists to ensure / check understanding
- Staff Appraisal Template
- Development plans to set objectives
- Competency Spot Check Assessment
- Training/Competency Matrix

7.3 Awareness

We ensure that all employees are aware of all policies and their contribution to the effectiveness of the Quality Management System through:

- Notice Boards
- Employee Handbook
- Awareness Training
- Induction
- CPD
- Environmental Training

7.4 Communication

For internal staff the company notice board is a source of information and is updated regularly to ensure that all information is correct. This is accessible by all staff.

Any communication which is sent external via email is designated through the appropriate line manager.

For external persons, the company internet is a source of information and is updated regularly to ensure that information is up-to-date. An environmental bulletin is created and distributed on a regular basis.

7.5 Documented Information

7.5.1 General

PTUK demonstrates documented compliance to ISO 9001:2015 and ISO14001:2015 (or any other standard in line with Annex SL Structure) through this Business Management System Manual (which includes processes & procedures) on an electronic system which is available on the company intranet / access drive to all employees. All information is electronic and only accessible via the document owner for amendment.

7.5.2 Creating and updating

The creation of documentation to support the Business Management System is primarily the responsibility of the designated “Quality Management Team Representative”.

Identification will be sought by a document number, date and author. To aid the approval and suitability of documents, the Managing Director of PTUK authorises the release and delegates any training required to the “The Quality & Environmental Management Team”.

7.5.3 Control of documented information

All documentation is controlled by version and date and is listed on a “Master Document List”.

PTUK has data protection in place to avoid the loss of confidentiality, improper use or loss of integrity. Key office computers are backed up daily to tape on a local server. Remote office computers / laptops are backed-up monthly to suitable magnetic or digital media.

Control of documents can be seen on the Master Document List and encompasses the following elements:-

- Distribution, Access, Retrieval and use
- Storage and preservation, including preservation of legibility
- Control of changes (e.g. version control)
- Retention and disposition

Documents can be retrieved by authorised personnel from the storage locations specified *and / or from folders on the network*. Customer records are identified by *customer name.*

On or after the retention period stated, the relevant records will be reviewed by The Quality Management Team and will either remain in-situ, be archived or destroyed.

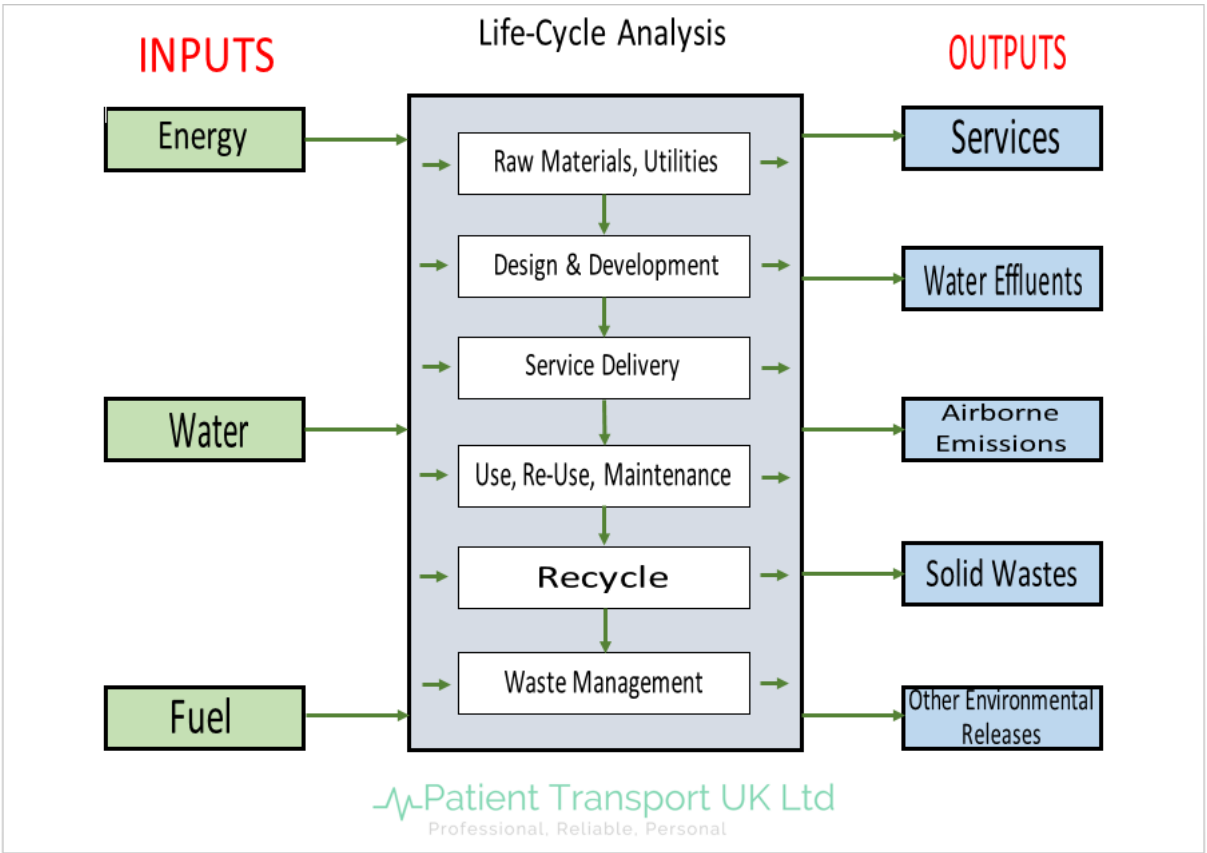
If records are to be destroyed, they will be disposed of in a controlled manner; *sensitive hard copies will be shredded and soft copies will be deleted from the system*. If records are to be archived, they will be identified and stored appropriately

Please see below document as demonstration of compliance:
Master Document List

8 Operation
8.1 Operational planning and control

PTUK has determined the requirements and controls implemented for all processes detailed in section 4.4. Any planned changes are controlled through section 6.3 (Planning for Changes)

We have processes in place to ensure that we mitigate any adverse effects within the products or services we provide.



8.2 Determination of requirements for products and services (Quality)
8.2.1 Customer Communication

Capability, facility and service information is supplied to customers via web site, brochures, email and through direct sales / personal contact.

Communications such as enquiries, quotes, orders and amendment details are appropriately stored and identified by customer and reference number.

Any technical documentation required for products / services offered by PTUK are forwarded to our clients on closure of the contract. The documentation is then filed within the client file.

Customer feedback is proactively sought via direct contact and satisfaction monitoring.

Complaints are documented and recorded.

Please see below document(s) as demonstration of compliance:

Doc039 - Patient Feedback Form.xlsx
Doc015 - Customer Complaints Form.docx
Doc016 - Customer Complaints Summary.docx

8.2.2 Determination of requirements related to products and services (Quality)

PTUK ensures that applicable statutory and regulatory requirements are met which can be evidenced within section 4.1 of this document.
Should we issue any legal documentation (i.e. calibration document – traced back to national standards) in connection with the products / services offered then this is forwarded to the clients at the closure of the contract. All documentation is filed within the client file for archive purposes.

8.2.3 Review of requirements related to products and services (Quality)

PTUK has processes in place to ensure that client details are collected at “Contract Review”. This is to ensure that all details are correct and any additional information is collected etc.

Any statutory and regulatory requirements applicable to the service / products offered are also documented within the contract review.

The contract review will be reviewed mid-way through the process to validate the client’s requirements.

Any change required either through client requirements or product / service design will be fully documented through the “Planning of changes” within section 6.1 of this document.

8.2.4 Emergency preparedness and response (Environment)

PTUK have established, implemented and maintained processes to prepare for emergency situations and to respond if they occur. The below are aspects of performing the organisations functions in an emergency:

- Maintain plans for preventing the emergency
- Maintain plans for reducing, controlling or mitigating its effects
- Maintain plan for taking other action in connection with the emergency

8.3 Design and development of products and services

PTUK has detailed processes for the design and development of products / services. The following elements are detailed within flowcharts explaining the processes:-

- Design and Development Planning
- Design and Development Inputs
- Design and Development Controls
- Design and Development Outputs
- Design and Development Changes

8.3.1 General

The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.

8.3.2 Design and development planning

In determining the stages and controls for design and development, the organization shall consider:
a) The nature, duration and complexity of the design and development activities;
b) The required process stages, including applicable design and development reviews;
c) The required design and development verification and validation activities;
d) The responsibilities and authorities involved in the design and development process;
e) The internal and external resource needs for the design and development of products and services;
f) The need to control interfaces between persons involved in the design and development process;
g) The need for involvement of customers and users in the design and development process;
h) The requirements for subsequent provision of products and services;
i) The level of control expected for the design and development process by customers and other relevant interested parties;
j) The documented information needed to demonstrate that design and development requirements have been met.

8.3.3 Design and development inputs

The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider:
a) Functional and performance requirements;
b) Information derived from previous similar design and development activities;
c) Statutory and regulatory requirements;
d) Standards or codes of practice that the organization has committed to implement;
e) Potential consequences of failure due to the nature of the products and services.

Inputs shall be adequate for design and development purposes, complete and unambiguous.
Conflicting design and development inputs shall be resolved.
The organization shall retain documented information on design and development inputs.

8.3.4 Design and development controls

The organization shall apply controls to the design and development process to ensure that:
a) The results to be achieved are defined;
b) Reviews are conducted to evaluate the ability of the results of design and development to meet requirements;
c) Verification activities are conducted to ensure that the design and development outputs meet the input requirements;
d) Validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;
e) Any necessary actions are taken on problems determined during the reviews, or verification and validation activities;
f) Documented information of these activities is retained.

NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.

8.3.5 Design and development outputs
The organization shall ensure that design and development outputs:
a) Meet the input requirements;
b) Are adequate for the subsequent processes for the provision of products and services;
c) Include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
d) Specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.
The organization shall retain documented information on design and development outputs.

8.3.6 Design and development changes
The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.
The organization shall retain documented information on:
a) Design and development changes;
b) The results of reviews;
c) The authorization of the changes;
d) The actions taken to prevent adverse impacts.

Please see below document(s) as demonstration of compliance:
Doc013 - Design and Development Flow Chart.docx

8.4 Control of externally provided products and services (Quality)
8.4.1 General
PTUK ensures that externally provided processes, products and services conform to specified requirements and also reviewed as part of PTUK's risk and mitigation matrix.

8.4.2 Type and extent of control of external provision (Quality)
PTUK have controls in place to ensure that external provisions are approved before using the service or product. This is done via the Supplier Quality Questionnaire together with the Supplier visit report.

Please see below document(s) as demonstration of compliance:
Doc010 - Approved Supplier List.xlsx
Doc011 - Supplier Quality Questionnaire.docx
Doc012 - Supplier Visit Report.docx

8.4.3 Information for external provision (Quality)
Communication of any applicable requirements which are deemed appropriate and are provided through the contract review with the provider. (I.e. T&C's, performance, competence etc.)

8.5 Production and service provision (Quality)
8.5.1 Control of production and service provision

PTUK ensures that controls are in place for conditions for production and service provision, including delivery and post-delivery activities.

8.5.2 Identification and traceability (Quality)

PTUK undertake scheduled stock takes and submit all delivery information to the financial team for cross referencing and records management. All products are logged including expiry and correct storage during this process. All PTUK vehicles are GPS tracked for traceability.

8.5.3 Property belonging to customers or external providers (Quality)

PTUK do not transport property belonging to external customers or providers

8.5.4 Preservation (Quality)

All products are stored in a locked and access managed secure stock room area. Items are signed in and out by authorised personnel only. Any products requiring temperature control are stored in refrigerated areas.

8.5.5 Post-delivery activities (Quality)

PTUK use feedback analysis, tracking data and handover confirmations to ensure service satisfaction in the post-delivery phase.

8.6 Release of products and services (Quality)

PTUK ensures that the appropriate documentation is provided to the client on release of the product / service and this is also retained for traceability.
Doc022 - Patient Handover Document.docx

8.7 Control of nonconforming process outputs, products and services (Quality)

The PTUK Management Action Log is used to identify non-conformances and any actual or potential shortfalls in quality standards or internal processes/ procedures, suggest improvements and track any actions to ensure improvements have taken place, or potential problems are avoided.

These areas are reviewed within the agenda for the Management Review meetings and typically cover the action taken to control and correct any non-conformances noting any consequences of the action taken and themes which may be evident. In terms of continual improvement, we also review the suitability, adequacy and effectiveness of our Business Management System.

PTUK has various processes and procedures in place to ensure that preventative action against nonconformities can be introduced, documented and seen through to completion in order to address the initial problem. The complex nature of the clients we work with demands that we have flexible, but effective, processes and procedures in place.

However, PTUK also uses internal and external audits and risk assessments to continuously improve its service delivery, financial, HR and operational functions.

Steps

- The Management Representative maintains and monitors the Action Log.
- If any person discovers a shortfall, or potential shortfall in the written processes/procedures or a problem in the practical application of them, the details must be documented in the Action Log. The relevant person who is responsible for the action is informed. Action required as a result of Customer Feedback, Customer Complaint, Information Security incident or Management Review is also logged and tracked via the company Action Log.
- Each entry in the Action Log to include:
    a. Sequential numbering
    b. Category of issue
    c. Person/Date recorded
    d. Overview of the issue, problem or concern
    e. Person responsible

f. Action taken
g. Date completed
h. Initialled when complete

For products the following actions must are also followed:-

- Segregation, containment, return or suspension of provision of products

The Senior Management Representative is responsible for checking the "non-conforming products or services form" and ensuring that people with allocated responsibilities are aware of them and actions are progressing.

Once all actions on a log sheet have been completed the Management Representative archives it as a Quality Record

Related records
Non-Conforming Products or Services
Management Review meeting records
Doc023 - Corrective and Preventative Action Log.xlsx

9 Performance Evaluation

9.1 Monitoring, measurement, analysis and evaluation

Monitoring is based on Risk and is linked to the risk & opportunities register.

9.1.1 General

PTUK has deemed the following elements (9.1.2, 9.2 & 9.3) for monitoring, measuring, analysis & evaluation to ensure the quality performance and the effectiveness of the quality management system.

9.1.2 Evaluation of compliance (Environmental)

PTUK ensures that compliance is reviewed regularly to ensure the business is meeting compliance obligations. This can be seen in section 4.1 of this business management system.

9.1.3 Customer Satisfaction (Quality)

PTUK collates data on customer satisfaction through various means. This includes customer contact, emails and customer satisfaction survey.

The customer satisfaction survey is sent to clients yearly, analysed and evaluated at the Management review meeting by "The Quality Management Team" as it is a reportable requirement.

Please see below document as demonstration of compliance:
Doc039 - Patient Feedback Form

9.1.4 Analysis and Evaluation (Quality)

Results of feedback which includes customer satisfaction questionnaire, internal audits, conformity of products & service, planning, suppliers, risk & opportunities matrix is evaluated through the management review meeting and actioned as applicable should any non-conforming areas be present.

9.2 Internal Audit

An internal audit schedule is prepared on an annual basis year and covers the requirements of any ISO standards in which PTUK wish to be certified. Internal audits are carried out through "risk or claused based" auditing.

Appropriate personnel are allocated to complete the internal audits and must record appropriate evidence for completeness. All audits completed must be authorised by The Quality Management Team as complete once any non-conforming areas have been dealt with (without any undue delay). Internal audit documentation must be kept and filed appropriately.

Please see below document as demonstration of compliance:

Doc024 - Internal Audit Report - Non Conformance.docx

Doc025 - Quality Problem Report.docx

9.3 Management Review

Management reviews take place on a monthly basis. The attendees present are "The Quality Management Team" and any other appropriate persons of the business.

All inputs / outputs are full documented and minutes taken in line with the requirements of the specific ISO standard in which PTUK wish to be certified. Any actions arising from the meeting must be completed without any undue delay and appropriate evidence filed with the Management review documentation.

Please see below document as demonstration of compliance:

Doc026 - Management Review Agenda.docx

10 Improvement

10.1 General

PTUK ensures that improvement processes are completed and actioned as necessary. Analysis methods include various elements which include:-

- Customer Satisfaction Analysis and Evaluation
- Internal Audits
- Planning changes to the Quality Management System, Products & Services
- 3rd party assessments for certification purposes
- Results of non-conforming products
- Risks & Opportunities

10.2 Nonconformity and corrective action

Should a nonconformity occur, including those arising from complaints, internal audits & external 3rd party assessment PTUK designate the appropriate "Quality Management Team" representative to ensure that corrective action including root cause analysis is completed and implemented to avoid any further occurrences. This is then analysed and should the risk to the business pose to be "high" then this is then entered onto the "Risk & Opportunities" matrix to assist in mitigating the risk to the business.

Should any non-conformance occur then the internal audit report / non-conformance report must be completed to ensure that a full analysis of the problem is resolved. Should any changes to the

Business Management System, Products or Services be required then the “Planning changes” document shall also be completed.

The corrective action plan summary must be completed, as this then forms part of the Management Review meeting.

Please see below document(s) as demonstration of compliance:
Doc023 - Corrective And Preventative Action Log.xlsx

10.3 Continual Improvement

Continual Improvement will be ongoing through various elements of the Business Management System which is encompassed within this document. The list below is not exhaustive:-

- Risk & Opportunities Analysis – Evaluated at several stages (clause 5.1, 6.1)
- Quality Policy / Objectives
- Planning of Changes
- Competency Matrix
- Customer Satisfaction
- Production & Service Provision (Supplier Evaluation)
- Internal Audits
- 3rd Party External Audits
- Management Review