

# Bitworks Design & Consultancy Quality Management System Part 1 - Quality Manual

This Quality Manual has been issued on the authority of the Senior Partners of Bitworks & Design Consultancy for the use of all staff, subcontractors, clients or regulatory bodies to whom Bitworks & Design Consultancy may be required to provide such information.

Author Mr Ian Bickerton Bitworks & Design Consultancy Quality Manager

Authorised Mr Mike Down Bitworks & Design Consultancy Senior Partner

 File No:
 BW\_001\_03\_C\_QMS-Part1-QM\_51\_IB\_01

 Version No:
 01

 Date:
 16.02.03

© 2003 by Bitworks Design & Consultancy, all rights reserved.

### **Document Control Sheet**

Title	This version	Date
Bitworks Design & Consultancy QMS	01	16.02.03
Part 1 - Quality Manual	File Number	No of Pages
	BW_001_03_C_QMS-Part1- QM_51_IB_01.doc	49

#### Abstract

The Bitworks Design & Consultancy Quality Management System is divided into four parts. This Quality Manual is Part 1 and describes the policies adopted by Bitworks Design & Consultancy.

This Quality Manual defines:

- The overall Quality Management System adopted by Bitworks Design & Consultancy;
- The organisation that has been developed to implement that Quality Management System;
- The associated documentation (e.g. Quality Processes, Quality Procedures and Work Instructions) that have been designed to enable Bitworks Design & Consultancy to carry out the Quality Management System.

The Quality Processes designed to meet these policies are contained in Part 2 and the details of the Quality Procedures and Work Instructions are in Parts 3 and 4.

Name	Function	Level
Mr Ian Bickerton	Quality Manager	Prepare
Mr Mike Down	Senior Partner	Approve

#### Keywords

Core Business Process, ISO 9001:2000, Policy, Quality, Quality Management System, Quality Manager, Quality Manual, Quality Procedure, Supporting Process, Work Instruction.

Approved			
	Mr Mike Down	Mr Ian Bickerton	Date:
	(Senior Partners)		

### Amendments

Changes in the organisation of Bitworks Design & Consultancy or the environment in which it operates, may necessitate modifications, amendments, insertions and/or deletions to the overall quality management adopted by Bitworks Design & Consultancy and its associated documentation (e.g. Quality Procedures and Work Instructions). The contents of this Quality Manual may, therefore, be altered on an as required basis. All changes shall be subject to QP 8 - Change Control. Changes shall be deemed operational following approval by the authorised person/s and published on the Bitworks Website www.bitworks-engineering.co.uk as a single point of reference for customers and employees.

No	Section	Amendment details	Date
01	All	First issue	16.02.03

### **Distribution List**

Printed copies of this Quality Manual will be made available on a temporary basis as and when required. The controlled QMS documents are available in PDF format on the Bitworks Design & Consultancy Website <u>www.bitworks-engineering.co.uk</u> providing one point source for Bitworks Customers and Employees.

### Contents

		.1
Docu	ment Control Sheet	.2
Amer	ndments	.3
Distri	bution List	.3
Conte	ents	.4
List o	f Illustrations	.7
List o	f Tables	.7
Abbre	eviations and Acronyms	.8
Refer	rences	.8
Bitwo	orks Design & Consultancy - Quality Policy	.9
1	INTRODUCTION1	0
1.1	Background1	0
1.2	Costs1	0
1.3	Scope1	0
	Dituente Desing 9 Consultance, expensional short	4
1.4	Bitworks Design & Consultancy - organisational chart1	I
1.5	Quality policy and objectives1	1
1.5	· · · <b>/</b>	
1.5	· · · J · · · · ·	
1.5 1.5	I	
1.5		3
1.5		
2	QUALITY MANAGEMENT SYSTEM1	4
2.1	Requirements1	4
	•	
2.2	Organisational goals1	5
2.3	Purpose1	5
2.4	Documentation1	6
2.4		
2.4		
2.4	•	
2.4		
2.4		
2.4	1.6 Project Quality Plans1	9

3	CUSTOMER SATISFACTION	.20
ļ	QUALITY MANAGEMENT SYSTEM (ISO 9001:2000 - 4) Conformance with ISO 9001:2000 Amendments Quality Manual administration Confidentiality	.21 .21 .21
4.1	General requirements (ISO 9001:2000 - 4.1)	.21
4.2 4.2 4.2	Documentation requirements (ISO 9001:2000 - 4.2).           2.1         General (ISO 9001:2000 - 4.2.1)           2.2         Quality Manual (ISO 9001:2000 - 4.2.2)           2.3         Control of documents (ISO 9001:2000 - 4.2.3)           2.4         Control of quality records (ISO 9001:2000 - 4.2.4)	.22 .22 .22
5	MANAGEMENT RESPONSIBILITY (ISO 9001:2000 - 5)	.24
5.1	Management commitment (ISO 9001:2000 - 5.1)	.24
5.2	Customer focus (ISO 9001:2000 - 5.2)	.24
5.3	Quality policy (ISO 9001:2000 - 5.3)	.24
5 /	Planning (ISO 9001:2000 - 5.4)	
5.4	4.1         Quality objectives (ISO 9001:2000 - 5.4.1)           4.2         Quality Management System planning (ISO 9001:2000 - 5.4.2)	.25
5.5 5.5	Responsibility, authority and communication (ISO 9001:2000 - 5.5)5.1Responsibility and authority (ISO 9001:2000 - 5.5.1)5.2Management representative (ISO 9001:2000 - 5.5.2)5.3Internal communication (ISO 9001:2000 - 5.5.3)	.26 .26
5.6 5.6	Management review (ISO 9001:2000 - 5.6)         6.1       General (ISO 9001:2000 - 5.6.1)         6.2       Review input (ISO 9001:2000 - 5.6.2)         6.3       Review output (ISO 9001:2000 - 5.6.3)	.27 .27
6	RESOURCE MANAGEMENT (ISO 9001:2000 - 6)	.29
6.1	Provision of resources (ISO 9001:2000 - 6.1)	.29
6.2	Human resources (ISO 9001:2000 - 6.2)           2.1         General (ISO 9001:2000 - 6.2.1)           2.2         Competence, awareness and training (ISO 9001:2000 - 6.2.2)	.29
6.3	Infrastructure (ISO 9001:2000 - 6.3)	.30
6.4	Work environment (ISO 9001:2000 - 6.4)	.30

7	7 PRODUCT REALISATION (ISO 9001:2000 - 7)			
7.1	Planning of realisation processes (ISO 9000:2000 - 7.1)	32		
<b>7.2</b> 7.2 7.2 7.2	<ul> <li>.1) 32</li> <li>.2 Review of requirements related to the product (ISO 9000:2000 - 7.2.2)</li> </ul>	33		
<b>7.3</b> 7.3 7.3 7.3 7.3 7.3 7.3 7.3	<ul> <li>Design and development inputs (ISO 9001:2000 7.3.2)</li> <li>Design and development outputs (ISO 9001:2000 - 7.3.3)</li> <li>Design and development review (ISO 9001:2000 - 7.3.4)</li> <li>Design and development verification (ISO 9001:2000 - 7.3.5)</li> <li>Design and development validation (ISO 9001:2000 - 7.3.6)</li> </ul>	34 35 35 36 36		
<b>7.4</b> 7.4 7.4 7.4	.2 Purchasing information (ISO 9001:2000 - 7.4.2)	37 38		
7.5. 7.5.	<ul> <li>.2 Validation of processes for production and service provision (ISO )1:2000 - 7.5.2)</li> <li>.3 Identification and traceability (ISO 9001:2000 - 7.5.3)</li> <li>.4 Customer property (ISO 9001:2000 - 7.5.4)</li> </ul>	38 39 39 40		
7.6	Control of monitoring and measuring devices (ISO 9001:2000 - 7.6)	41		
8	MEASUREMENT, ANALYSIS AND IMPROVEMENT (ISO 9001:2000 - 8)4	42		
8.1	General (ISO 9001:2000 - 8.1)	42		
<b>8.2</b> 8.2 8.2 8.2	.2 Internal audit (ISO 9001:2000 - 8.2.2)	42 42 43		
8.3	Control of non-conforming product (ISO 9001:2000 - 8.3)	43		
8.4	Analysis of data (ISO 9001:2000 - 8.4)	44		
<b>8.5</b> 8.5 8.5		44		

8.5.3	Preventive action (ISO 9001:2000 -	8.5.3)45
Annex A -	Bitworks organisation and responsibilities	
Annex B -	ISO 9001:2000 cross-check	

### **List of Illustrations**

Figure 1: Bitworks Design & Consultancy - organisational chart	.11
Figure 2: Quality loop	.14
Figure 3: Quality Management System	.16
Figure 4: Bitworks Design & Consultancy - organisational chart	.46

### **List of Tables**

Table 1: Bitworks Design & Consultancy's Quality Management System - documentation..17

Abbreviation	Definition	
СР	Core Business Process	
DCS	Document Control Sheet	
Bitworks	Bitworks Design & Consultancy	
HSE	Health & Safety Executive (UK)	
ISO	International Standards Organisation	
IT	Information Technology	
QM	Quality Manual	
QMS	Quality Management System	
QP	Quality Procedure	
SP	Supporting Process	
SQP	Section Quality Plan	
TQM	Total Quality Management	
WI	Work Instruction	

## **Abbreviations and Acronyms**

### References

Ref	Abbreviation/	Title	Issue date
	Reference		
1.	ISO 9001	Quality Management Systems - Requirements	2000
2.	ISO 10011	Guidelines for auditing quality systems	
		Part 1 - Auditing	1990
		Part 2 - Qualification criteria for quality systems auditors	
		Part 3 - Management of audit programs	1991
3.	BitworksMAA_ 02.doc	Bitworks Design & Consultancy's Memorandum and Articles of Association	1994

### **Bitworks Design & Consultancy - Quality Policy**

Within Bitworks Design & Consultancy we are committed to provide products and services which meet the customers' specified contractual and project requirements. We are totally committed to setting and achieving quality, and in all respects, the specified requirements and reasonable expectations of our customers.

Bitworks Design & Consultancy shall develop and maintain a Quality Management System that conforms to the requirements of ISO 9001:2000 so that we can provide and maintain a consistently high quality in all work we undertake. Our Quality Management System shall ensure that proper communication, work control and accountable records are generated for all work undertaken.

All employees of Bitworks Design & Consultancy are charged with promoting these aims and are required to familiarise themselves with the contents of this Quality Manual which defines the Quality Management System that has been established and adopted as the means for achieving these declared objectives. Everyone connected with Bitworks Design & Consultancy shall be supported according to their individual needs for personal development, training and facilities.

The Quality Manager based at the Bitworks Design & Consultancy Cheltenham Office is the appointed management representative responsible for monitoring and ensuring the correct and effective implementation of Bitworks Design & Consultancy Quality Management System as a whole.

Total Quality Management **shall** be applied to every aspect of our activity and quality **shall** be the responsibility of everyone, in every activity, throughout Bitworks Design & Consultancy.

Mr Mike Down & Mr Ian Bickerton Bitworks Senior Partners

9

### 1 INTRODUCTION

### 1.1 Background

Bitworks Design & Consultancy (Bitworks) established in 1997, an engineering partnership with the following specialist areas and expertise:

- Webpage design with database interaction
- PC Application Software with advanced MMI
- Scientific, Medical or General Database Applications
- Speech Recognition and Audio Signal Processing
- Embedded Product Software in ANSI C or Assembler
- Electronic Design, PC Cards PCI, PMC, migration of ISA to PCI
- Mathematical Algorithm development and product implementation
- Driver Software for PCI/PMC and legacy ISA designs, common software operating with Windows 95/98/NT/2k & XP

Bitworks is customer focused to provide quality engineering at the right price.

Bitworks aim is to provide value for money engineering consultancy in support of our customer's product or service. We take pride in being reliable and friendly in day-to-day dealings with our customers, good communication equates to the delivery of improved product quality.

### 1.2 Costs

Each contract budget is carefully prepared to suit the circumstances. Each contract is carefully analysed and accurate costing programmed accordingly. A financial breakdown is provided to the customer together with a summary of any programme risks, and it is only by mutual consent that any deviation is allowed from the agreed budget.

If from our experience and knowledge it is felt that a course of action or design approach is inappropriate, we will advise the customer accordingly. We will not embark on a project if circumstances point to a sub standard result. From the first brief to the final event, production, or programme every contract is overseen and carefully controlled through each design stage. A nominated Bitworks Project Manager will be appointed with overall responsibility to deliver the programme and meet all customer requirements.

Medical applications are a special case, **no profit is permitted** to be charged against any project with a medical application. This includes Information Technology application in General Practice or NHS Hospitals. All medical engineering work is at cost, estimates are based on average IEE salary indexes for the UK.

### 1.3 Scope

This Quality Manual defines:

- The overall quality policy adopted by Bitworks
- The organisation that has been developed to implement this quality policy
- The documentation (i.e. Quality Processes, Quality Procedures & Work Instructions) that has been designed to enable Bitworks carry out this policy

Other than the permissible exclusions shown in the relevant parts of the text, the Bitworks Quality Manual conforms to the requirements of ISO 9001:2000 (Ref. 1). It takes into consideration the requirements of Bitworks Memorandum and Articles of Association (Ref. 2), together with all other applicable national, European and international standards. If there are any discrepancies between the Bitworks Quality Manual and these other directives/standards, the requirements of the Bitworks Quality Manual shall take priority.

Changes in Bitworks organisation or the environment in which Bitworks organisation is operating, may necessitate modifications, amendments, insertions and deletions to Bitworks Quality Procedures and associated responsibilities. The contents of this Quality Manual may, therefore, be altered on an 'as required' basis. Changes shall be deemed operational following approval by the authorised person/s and published on the Bitworks website www.bitworks-engineering.co.uk.

Certain technical terms and usage in this Quality Manual, although only reflecting the masculine gender, are, in fact, the parlance of the field and should be interpreted to apply equally to both sexes.

### 1.4 Bitworks Design & Consultancy - organisational chart



Figure 1: Bitworks Design & Consultancy - organisational chart

### 1.5 Quality policy and objectives

### 1.5.1 Policy

Bitworks shall define and manage the processes necessary to ensure that all project deliverables conform to customer requirements. As a means of continually improving project performance, Bitworks shall establish a Quality Management System covering the requirements of ISO 9001:2000. This QMS shall be implemented, maintained, continually improved and have the full support of the Senior Partners.

Bitworks shall prepare procedures that describe the processes required to implement the Quality Management System. These shall include:

- Core Business Processes and Supporting Processes
- Quality Procedures that describe the methods adopted to manage the Core Business Process and Supporting Processes
- Work Instructions that describe the operating methods, practice and control of the Core Business Process and Supporting Processes

### 1.5.2 Objectives

The main objective of the Bitworks Quality Management System is to ensure that company activities, whether they are organisational (e.g. management and organisation) or technical (e.g. design work, testing, simulation) comply with the Quality Manual and the Quality Plans.

In cases of non-compliance, (e.g. if part of the design work is not carried out in accordance with the appropriate Work Instructions), a problem solving process shall be executed by the Project Manager. This process shall include the location of root causes, remedial action, review of Bitworks procedures and, if necessary, their adjustment and modification.

The Quality Manager plays an important part in this process. Her/His role shall be to suggest alternative solutions and help the Senior Partners to take the necessary remedial action. If no effective corrective action is taken, the Quality Manager has the duty to record the non-compliance which will be reported to the Customer by the Project Manager.

Summarised, the Quality Management System shall include:

- Clear responsibilities for each activity and development task
- Confirmation that each activity is defined and controlled by a Quality Procedure
- Confirmation that staff are trained to the requirements listed in the Quality Manual
- Confirmation that compliance with the processes and procedures detailed in the Quality Manual are audited
- Confirmation that remedial action is taken whenever appropriate
- Confirmation that the Quality Processes, Quality Procedures and Work Instructions contained in the Quality Manual are regularly reviewed

### 1.5.3 Implementation

Quality management in Bitworks is based on the Quality Management System described in ISO 9001:2000. The purpose of the quality system is to define the policy, organisation and responsibilities for the management of quality within Bitworks.

The most important aspects of Bitworks Quality Management System are to be found in the Bitworks Quality Manual (i.e. this document) which describes, in detail, how the main elements of ISO 9001:2000 are catered for. The Quality Manual is then supported by individual Quality Plans for each major contract/document as required, Quality Processes, Quality Procedures and Work Instructions.

All Bitworks personnel shall be advised that this Quality Manual is published on the Bitworks website <u>www.bitworks-engineering.co.uk</u> and the objectives of the manual shall be explained by the Bitworks Quality Manager as part of their induction to Bitworks.

### 1.5.4 Overall responsibility

All those who have a leading role within Bitworks have a day-to-day responsibility for ensuring conformance to the requirements and rules stated in this Quality Manual.

However, the responsibility of ensuring that Bitworks has a quality policy and for ensuring that an organisation with the necessary resources is in place to implement the policy shall always lie with the Senior Partners.

### **1.5.5 Responsibility for contract quality**

The responsibility for the development of contract quality rests with Bitworks Senior Partners through their individual Project Managers.

The responsibility for ensuring that the product conforms to the defined quality requirements in this manual lies with **all** Bitworks personnel.

Specialised areas of operation and technical expertise may be required to meet the needs of Bitworks. In some cases these will have to be provided externally via a subcontractor. In **all** cases these subcontractors shall be required to supply and prove that their Quality Management System is in accordance with the principles of ISO 9001:2000.

### 1.5.6 Responsibility for the Quality System

The Quality Management System forms an integral part of the overall Bitworks management and the role of the Quality Manager within the company is to provide confidence that application of contract management (as described in this Quality Manual) is efficient, comprehensive and effective in ensuring that Bitworks - and every section - delivers the right product:

- on time
- to the agreed specifications
- within budget

The Senior Partners have appointed the Quality Manager to implement and maintain Bitworks quality system. The Quality Manager has the responsibility and the authority to ensure that adequate procedures, plans and instructions are drawn up so as to provide a common approach to quality assurance throughout Bitworks and to ensure that the quality system is continuously monitored and improved by means of internal audits and management reviews.

### 2 QUALITY MANAGEMENT SYSTEM

### 2.1 Requirements

The Bitworks Quality Management System (QMS) is the organised structure of responsibilities, activities, resources and events that together provide procedures and methods of implementation to ensure the capability of Bitworks meets the quality requirements of our customers.

Bitworks has to develop, establish and implement a QMS in order to ensure that the overall objectives and policies stated in Bitworks Memorandum of Articles and Association are met.

To achieve these requirements, Bitworks involves all phases of the well known quality loop (see Figure 2) from the initial identification of the requirement to the final satisfaction of the customer's requirements and expectations.



Figure 2: Quality loop

Within Bitworks an effective QMS ensures that all activities are fully understood, controlled and documented and that everyone knows exactly what and how to execute a task following one of the Bitworks Work Procedures or Instructions.

There are 4 main requirement sections making up the ISO 9001:2000 standard ranging from how to control a design process to how to audit an activity - but the most important element is the first one which demands that **everyone** shall be involved in quality in order for it to succeed and that it **must** be management led and that there **must** be a commitment to quality - **at the highest level**.

Within Bitworks we have this commitment. It stems from the Bitworks decisions in this respect and manifests itself throughout Bitworks management, at all levels.

### 2.2 Organisational goals

The primary goal of Bitworks shall, at all times, be the quality of the end product and service. To succeed, Bitworks must be able to offer products and services that:

- Meet the need, use and purpose as defined in Bitworks Memorandum and Articles of Association
- Satisfy the customer's requirements and expectations
- Comply with applicable international, European and national quality standards and specifications

In order to meet these objectives, Bitworks has to organise itself in such a way that the technical, administrative and human factors affecting the quality of Bitworks products and services are always under control.

It is **imperative** that this control is orientated to the reduction, elimination and - of paramount importance - the prevention of quality deficiencies. The Bitworks QMS, therefore, has to be developed and implemented for the purpose of accomplishing the objectives set out in Bitworks Memorandum and Articles of Association.

Above all, and to achieve maximum effectiveness, it is essential that this QMS is designed so that it is appropriate to the type of contract and services being offered by Bitworks.

Demonstration of the continued success of the QMS shall be achieved via regular audits and reviews.

### 2.3 Purpose

The purpose of a QMS is to ensure that the end product (i.e. the deliverable) conforms to the customer's (i.e. user's), contractual requirements.

Bitworks QMS, therefore, involves all Bitworks functions, wherever and however instigated (e.g. Senior Partner, Project Manager, etc.) that directly, or indirectly, effects Bitworks deliverables and contracts.

In essence, this QMS essentially consists of the documented rules, procedures and instructions prepared in accordance with ISO 9001:2000. These are stated in this Quality Manual (QM) as well as the associated Core Business Process (CP), Supporting Processes (SPs) Quality Procedures (QPs) and Work Instructions (WIs). The Bitworks audit team

(consisting of the Senior Partners, Quality Manager and the Partnership Secretary) plus Project Manager's may decide if additional documents are required for individual Projects. In these cases, the requirement for an additional document shall be clearly stated and rules developed. This following section of the manual describes Bitworks QMS and demonstrates how it meets the requirements of ISO 9001:2000.

### 2.4 Documentation



### Figure 3: Quality Management System

A QMS can only be effective if it is fully documented, understood and followed by all. Within Bitworks QM there are four levels of documentation within a QMS, and these are structured as shown in Figure 3.

Part 1	Quality Manual	The main policy document that establishes the Bitworks QMS and how it meets the requirements of ISO 9001:2000.
Part 2	Quality Processes	The Core Business Process plus Supporting Processes that describe the activities required to implement the Bitworks QMS and to meet the policy requirements made in the QM.
Part 3	Quality Procedures	A description of the method by which quality system activities are managed
Part 4	Work Instructions	A description of how a specific task is carried out

## Table 1: Bitworks Design & Consultancy Quality Management System documentation

### 2.4.1 The Quality Manual

Management within Bitworks is based on the quality system described in ISO 9001:2000. The purpose of the Bitworks QMS is to define the policy, organisation, and responsibilities for the management of quality within Bitworks.

The most important aspects of the Bitworks QMS are to be found in the Bitworks QM which describes, in detail, how the sections of ISO 9001:2000 are catered for using CPs, SPs, QPs, WIs and individual Section Quality Plans (SQPs) for each section or major deliverable that support the QM.

Bitworks QM provides a definitive statement of the policy, objectives, operating systems and procedures established by Bitworks for use in all projects managed by our organisation.

The QM describes a number of systematic controls and procedures for the staff in fulfilling their duties and responsibilities. It defines the lines of traceable accountability and responsibility and exists primarily as an internal management control document. It recognises the established elements of modern formalised quality management as expressed in national and international standards and as appropriate to the nature of the work undertaken.

The QM also stands as a formal statement of Bitworks QMS, which has been established in response to the specified system requirements. As such, it provides a statement of commitment to customers (or external approval and/or regulatory bodies) to which Bitworks may be required to provide such information.

### 2.4.2 Quality Processes

The Bitworks QMS relies on the eight quality management principles contained in ISO 9001:2000 to enable a continual improvement of our business, our overall efficiency and to make us capable of responding to customer needs and expectations. These eight principles are:

- **Customer focused organisation** Bitworks depends on our customers and is committed to understanding, anticipating and responding to all customer requirements with product and service excellence.
- Leadership To establish unity of purpose, direction, and create the environment in which people can become fully involved in achieving Bitworks objectives.
- **Involvement of people** Bitworks have created an environment which makes every employee a team member and encourages participation in achieving our goals.
- **Process approach** Achieved by relating resources and activities to Customer requirements.
- System approach to management Identifying, understanding and managing a system of interrelated processes to achieve the stated objective.
- **Continual improvement** Continual improvement is an important and permanent objective of Bitworks.
- Factual approach to decision making Effective decisions are based on the logical and intuitive analysis of data and information.
- **Mutually beneficial supplier relationships** Mutually beneficial relationships between Bitworks and its suppliers enhance the ability of both organisations to create value.

The organisational processes making up the Bitworks QMS comprise a Core Business Process (CP) (describing the end to end activities involved in Bitworks project management and the production of contract deliverables) supplemented by a number of Supporting Processes (SPs) which describe the infrastructure required to complete Bitworks projects on time and within budget.

To ensure achievement of process objectives, a process owner with full responsibility and authority for managing the process and achieving process objectives shall be nominated, currently this responsibility lies with the Project Manager working in concert with the Quality Manager.

Bitworks processes are listed in Part 2 (Quality Processes) of the QM.

### 2.4.3 Quality Procedures

Quality Procedures (QPs) form the bulk of the QMS and describe how the policy objectives of the QM can be met in practice and how these processes are controlled.

QPs contain the basic documentation used for planning and controlling all activities that impact on quality. For example, procedures for customer complaints, project review, etc.

Each QP is unique as it contains details of procedures directly applicable to Bitworks. The QPs must, of course, cover the specific requirements contained in ISO 9001:2000, although in reality they often cover more as they are an efficient method of controlling every aspect of Bitworks business.

These documented procedures are made available in electronic format and published on the Bitworks website <u>www.bitworks-engineering.co.uk</u> for use inside and outside Bitworks places of work.

Some procedures may contain data or information, the knowledge of which must remain restricted to Bitworks. These procedures are not included in the QM, beyond their title and reference number.

Current Bitworks Quality Procedures are listed in Part 3 to the QMS.

### 2.4.4 Work Instructions

Work Instructions (WIs) describe how to perform specific operations and are produced for all of the relevant activities of Bitworks so as to ensure that the whole partnership can work to the same format. They describe how individual tasks and activities are to be carried out.

WIs describe in detail, procedures such as what is to be done, who should do it and when it has to be completed. They can, for example, cover simple issues such as making travel and hotel arrangements to more complex issues such as the contents and structure of Bitworks Software Design Documents.

They are produced for all of Bitworks relevant activities so as to ensure that the whole company can work to the same format. Current Bitworks WIs are listed in Part 4 of the QMS.

### 2.4.5 Records

Records provide objective evidence of and demonstrate conformance to specified requirements contained in the QMS. Normally records are retained for five years - except as required by law.

### 2.4.6 Project Quality Plans

For larger and more complex projects/contracts, project-specific Quality Plans may have to be produced. These are effectively a subset of the QM and describe additional procedures and controls that will have to be applied. The production of these Quality Plans shall be co-ordinated with the Project/Contract Manager concerned.

### **3 CUSTOMER SATISFACTION**

From the customer's point of view, Bitworks QMS **must** provide them with a level of confidence in the ability of Bitworks to deliver the desired quality as well as the consistent maintenance of that quality.

To be effective, Bitworks QMS shall need to ensure:

- That objective evidence is provided, (in the form of information and data), concerning the quality of the system and the quality of Bitworks products and services
- · Consideration has been given to the risks related to deficient products and services
- Consideration has been given to the risks pertaining to the health and safety of people
- Costs due to design deficiencies (including rework, re-processing and loss of production) have been considered

Bitworks QMS shall be designed and structured so that:

- It meets the customers needs and expectations
- It provides an effective management resource in the optimisation and control of quality in relation to risk, cost and benefit considerations
- The system is well understood and effective
- Emphasis is placed on problem prevention rather than dependence on detection after occurrence

### 4 QUALITY MANAGEMENT SYSTEM (ISO 9001:2000 - 4)

### Conformance with ISO 9001:2000

Subsequent sections of this QM describe the arrangements or systems that have been established to meet the specified requirements and are presented as far as possible in similar order to those in ISO 9001:2000. Not all requirements specified in ISO 9001:2000 are addressed in the Bitworks QM because in certain cases there is no relevance to the operation of Bitworks and its work (see Annex B - QMS to ISO 9001:200 cross-check for further details).

### Amendments

Changes in the Bitworks organisation or the environment in which the Bitworks organisation is operating may necessitate modifications, amendments, insertions and deletions to the overall QMS adopted by Bitworks and as described in this QM. The contents of QM and its associated documentation (i.e. CPs, SPs, QPs and WIs) may, therefore, be altered as necessary and on an as required basis. All changes shall be subject to a formal review and agreement process (see QP 8 - Change Control). Changes shall be deemed operational following approval by the authorised person/s and published as updated sections/annexes of the QM.

### **Quality Manual administration**

The Quality Manager shall review the effectiveness and suitability of QMS at least twice a year. As well as the QMS documentation, the whole scope of this manual shall also be reviewed. Where the system is found to be ineffective as a result of the changing needs of Bitworks business operations and its stakeholders, amendments shall be made to the QM.

Amendments shall be circulated to all registered holders of controlled copies who shall be responsible for updating their copies. When the sum of the amendments involve changing more than ten pages of the manual, the Senior Partners shall authorise the re-issue of the whole QM. Every issue replaces and cancels all previous issues and amendments. A number in accordance with QP 1 - Document Control shall identify each issue and revision. These issue/amendment numbers shall be clearly shown on the front cover of all of Bitworks quality documentation and included in the Document Control Sheet (DCS).

### Confidentiality

This QM is the intellectual property of Bitworks and may not be copied in whole or part, or transmitted to any third party without the express written permission of the Quality Manager.

The following sections of this QM are modelled on ISO 9001:2000 and each section, subsection, etc. directly corresponds (in terms of number and content) with the ISO equivalent number.

### 4.1 General requirements (ISO 9001:2000 - 4.1)

Bitworks shall define and manage the processes necessary to ensure that all project deliverables conform to customer requirements.

As a means of continually improving project performance, Bitworks shall:

- Establish a QMS covering the requirements of ISO 9001:2000
- Prepare procedures that describe the processes required to implement the QMS

### 4.2 Documentation requirements (ISO 9001:2000 - 4.2)

### 4.2.1 General (ISO 9001:2000 - 4.2.1)

Bitworks QMS documentation shall include:

- Statements regarding quality policy and quality objectives
- Documented procedures, that clearly describe the sequence of processes necessary to ensure conformance with ISO 9001:2000
- Documented instructions to ensure the effective operation and control of processes and quality records

### 4.2.2 Quality Manual (ISO 9001:2000 - 4.2.2)

### 1. Bitworks policy and objectives

Bitworks shall establish and maintain a QM which shall include:

- details of any ISO 9001:2000 exclusions
- details of associated documented procedures
- their sequence and interaction

### 2. Responsibilities

The Quality Manager is responsible for operating the QMS, ensuring that the QM is fully and effectively implemented and for co-ordinating the writing availability of the necessary processes, procedures and instructions.

### 3. Implementation

QP 5 - Quality Management System Review.

### 4.2.3 Control of documents (ISO 9001:2000 - 4.2.3)

### 1. Bitworks policy and objectives

Bitworks shall establish QMS level procedures for controlling documents required for the operation of the QMS. These procedures shall ensure that:

- Documents are approved for adequacy prior to release
- Documents are reviewed, updated as necessary and re-approved
- The relevant versions of documents are available at locations where activities essential to the effective functioning of the QMS are performed
- Obsolete documents are removed from all points of issue and use, or otherwise controlled to prevent unintended use
- Any obsolete documents retained for legal or knowledge-preservation purposes are suitably identified

A master list identifying the current revision status of documents, shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

Documents shall be legible, readily identifiable and retrievable. Applicable documents of external origin shall be identified and recorded (see 4.2.4).

### 2. Responsibilities

The Partnership Secretary is responsible for the overall planning of document control procedures throughout Bitworks.

### 3. Implementation

QP 1 - Document Control.

### 4.2.4 Control of quality records (ISO 9001:2000 - 4.2.4)

### 1. Bitworks policy and objectives

Bitworks shall maintain quality records appropriate to the company to demonstrate conformance to the requirements and the effective operation of the QMS. Bitworks shall establish and maintain QMS level procedures for the identification, storage, retrieval, protection, retention time, and disposition of quality records.

### 2. Responsibilities

The Quality Manager is responsible for maintaining quality records demonstrating conformance to the requirements and the effective operation of the QMS.

In the case of Software Development, the Project Manager is responsible for documenting the four phases from Analysis, Design, Code to Test, see QMS Part 4 WI 1.

#### 3. Implementation

SP 5 - Documentation QP 5 - Quality Management System Review. WI 1 - Software Development

### 5 MANAGEMENT RESPONSIBILITY (ISO 9001:2000 - 5)

### 5.1 Management commitment (ISO 9001:2000 - 5.1)

### 1. Bitworks policy and objectives

Bitworks management (Senior Partners, Quality Manager and Partnership Secretary) shall demonstrate their commitment by:

- Carrying out regular management reviews of the QMS and its associated documentation aimed at ensuring the continual improvement of the system (also see 5.6)
- Establishing the quality policy and quality objectives (also see 5.3 and 5.4.1)
- Ensuring the availability of necessary resources (also see 6.1)
- Ensuring adequate focus on customer requirements throughout Bitworks
- Ensuring that all staff are aware of the importance of meeting customer, regulatory and legal requirements

### 2. Responsibilities

The Bitworks Executive Board is responsible for demonstrating their commitment to quality and for supporting management in achieving that commitment.

### 3. Implementation

The Bitworks QM sections 5-8 together with its supporting annexes.

### 5.2 Customer focus (ISO 9001:2000 - 5.2)

#### 1. Bitworks policy and objectives

With the overall aim of achieving customer satisfaction, Bitworks shall ensure that:

- Customer needs and expectations are determined and converted into requirements
- Customer requirements are fully understood and met (also see 7.2.1)
- Customer satisfaction is enhanced

#### 2. Responsibilities

Bitworks management has overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

Bitworks QMS Part 1 (i.e. this Quality Manual).

### 5.3 Quality policy (ISO 9001:2000 - 5.3)

### 1. Bitworks policy and objectives

Bitworks shall establish its quality policy and ensure that it:

- Is appropriate for the needs of Bitworks and its customers
- Includes a commitment to meeting requirements and continual improvement
- Provides a framework for establishing and reviewing quality objectives
- Is communicated, understood and implemented throughout Bitworks

• Is regularly reviewed for continuing suitability

### 2. Responsibilities

Bitworks management has overall responsibility for establishing, implementing and maintaining this activity.

### 3. Implementation

Bitworks QM Section 1.5.

### 5.4 Planning (ISO 9001:2000 - 5.4)

### 5.4.1 Quality objectives (ISO 9001:2000 - 5.4.1)

### 1. Bitworks policy and objectives

Bitworks shall establish quality objectives at each relevant function and level. These quality objectives shall be consistent with the quality policy and the commitment to continual improvement. Quality objectives shall include those needed to meet product and service requirements.

#### 2. Responsibilities

Bitworks management has overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

Bitworks QM Section 1.5.

### 5.4.2 Quality Management System planning (ISO 9001:2000 - 5.4.2)

#### 1. Bitworks policy and objectives

Bitworks shall identify and plan the activities and resources needed to achieve quality objectives. This planning shall be consistent with other requirements of the QMS and the results shall be documented.

Planning shall cover the:

- Processes required in the QMS (and any reduction in scope of this international standard)
- Realisation processes and resources needed, identifying quality characteristics at different stages, to achieve the desired results
- Verification activities, criteria for acceptability and the quality records needed

Planning shall ensure that organisational change is conducted in a controlled manner and that the QMS is maintained during this change.

#### 2. Responsibilities

Bitworks management has overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

Bitworks QM Sections 1.5, 2.1 and 2.2.

## 5.5 Responsibility, authority and communication (ISO 9001:2000 - 5.5)

### 5.5.1 Responsibility and authority (ISO 9001:2000 - 5.5.1)

### 1. Bitworks policy and objectives

Bitworks shall define the roles and their interrelations, responsibilities and authorities in order to facilitate effective quality management and this information shall be communicated throughout Bitworks. Organisational freedom necessary to perform tasks that affect quality shall be defined.

### 2. Responsibilities

Bitworks management has overall responsibility for establishing, implementing and maintaining this activity.

### 3. Implementation

Bitworks QM, Annex A - Duties and responsibilities.

### 5.5.2 Management representative (ISO 9001:2000 - 5.5.2)

### 1. Bitworks policy and objectives

The Senior Partners shall appoint a member of the management who, irrespective of other responsibilities, shall have defined authority that includes:

- Ensuring that the Bitworks QMS is implemented and maintained in accordance with the requirements of this international standard
- Reporting to Bitworks management on the performance of the QMS, including needs for improvement
- Ensuring awareness of customer requirements throughout Bitworks
- Liaising with external parties on matters relating to the Bitworks QMS

### 2. Responsibilities

The Quality Manager reports to the Senior Partners and is independent of all contractual and project responsibilities that may adversely affect quality performance. He is responsible for ensuring that the QM and its associated CPs, SPs, QPs and WIs (making up the Bitworks QMS) are kept up-to-date and are administered and implemented correctly and efficiently according to the quality policy laid down by the Senior Partners.

The Quality Manager has the overall responsibility for ensuring that the policies set out in this QMS are understood, implemented and maintained at all levels in the organisation and that the company works towards achieving its vision and key objectives.

The Quality Manager represents Bitworks in all matters relevant to the QMS as established by customer, regulatory and ISO 9001:2000 requirements. She/He is responsible for ensuring that the system is effectively implemented and maintained, and reports on the performance of the QMS at management review meetings.

The Quality Manager is the prime point of liaison with certification bodies and customers' quality management representatives.

### 3. Implementation

Details of the Quality Manager's duties and responsibilities are included at Annex A to the QM.

### 5.5.3 Internal communication (ISO 9001:2000 - 5.5.3)

### 1. Bitworks policy and objectives

Bitworks shall establish and maintain procedures for internal communication between the various levels and functions regarding the QMS and its effectiveness.

### 2. Responsibilities

The Quality Manager has overall responsibility for establishing, implementing and maintaining this activity.

### 3. Implementation

QP 10 - Training.

### 5.6 Management review (ISO 9001:2000 - 5.6)

### 5.6.1 General (ISO 9001:2000 - 5.6.1)

### 1. Bitworks policy and objectives

Bitworks shall establish a process for the periodic review of the QMS. It shall be reviewed to ensure its continuing suitability, adequacy and effectiveness. The review shall evaluate the need for changes to Bitworks QMS, including policy and objectives and continues to provide customer satisfaction.

#### 2. Responsibilities

The Quality Manger is responsible for ensuring that quality records are maintained in a systematic and presentable form.

All staff are responsible for ensuring that they provide the necessary records as required from their involvement in implementing the quality systems.

#### 3. Implementation

QP 5 - Quality Management System Review.

### 5.6.2 Review input (ISO 9001:2000 - 5.6.2)

### 1. Bitworks policy and objectives

The review input of the QMS shall include (but not be limited to):

- Results and follow-up actions from earlier management reviews
- Results of previous internal, customer and third party audits
- Self-assessment results
- Analysis of customer feedback
- Analysis of process performance
- Analysis of product conformance
- The current status of preventive and corrective action

- Supplier performance
- Changes that could affect the QMS
- Recommendations for improvement

### 2. Responsibilities

The Quality Manger is responsible for ensuring that quality records are maintained in a systematic and presentable form.

All staff are responsible for ensuring that they provide the necessary records as required from their involvement in implementing the quality systems.

### 3. Implementation

QP 5 - Quality Management System Review.

### 5.6.3 Review output (ISO 9001:2000 - 5.6.3)

#### 1. Bitworks policy and objectives

- The output of the management review shall include:
- Improved product and process performance
- Confirmation of resource requirements and organisational structure
- Market needs
- Risk management
- Change control
- Continued compliance with the relevant statutory and regulatory requirements

Results of management reviews shall be recorded. (see 4.2.4).

#### 2. Responsibilities

The Quality Manger is responsible for ensuring that quality records are maintained in a systematic and presentable form.

All staff are responsible for ensuring that they provide the necessary records as required from their involvement in implementing the quality systems.

#### 3. Implementation

QP 5 - Quality Management System Review.

### 6 RESOURCE MANAGEMENT (ISO 9001:2000 - 6)

### 6.1 **Provision of resources (ISO 9001:2000 - 6.1)**

### 1. Bitworks policy and objectives

Bitworks shall determine and provide in a timely manner, the resources needed to establish and maintain (and continually improve) their QMS so as to enhance customer satisfaction by meeting customer requirements.

### 2. Responsibilities

The Senior Partners has overall responsibility for establishing, implementing and maintaining this activity.

### 3. Implementation

SP 1 - Human Resources SP 3 - Budget and Finance

### 6.2 Human resources (ISO 9001:2000 - 6.2)

### 6.2.1 General (ISO 9001:2000 - 6.2.1)

### 1. Bitworks policy and objectives

Bitworks shall only assign personnel who are competent (e.g. education, training, skills and experience, etc.). Their responsibilities shall be defined in Annex A to this Quality Manual.

### 2. Responsibilities

The Senior Partners has overall responsibility for establishing, implementing and maintaining this activity.

### 3. Implementation

SP 1 - Human Resources

### 6.2.2 Competence, awareness and training (ISO 9001:2000 - 6.2.2)

### 1. Bitworks policy and objectives

Bitworks shall establish and maintain system level procedures to:

- Determine competency and training needs
- Provide training to address identified needs
- Evaluate the effectiveness of training at defined intervals
- Maintain appropriate records of education, training, skills, and experience (see 4.2.4)
- Ensure that the necessary expertise and levels of skills, etc. are available to handle the expected workload and range of activities

Bitworks shall establish and maintain procedures to make its employees at each relevant function and level aware of:

• The importance of conformance with the quality policy, and with the requirements of the Quality Management System

- · The significant impact of their work activities on quality, actual or potential
- The benefits of improved personal performance
- Their roles and responsibilities in achieving conformance with the quality policy and procedures and with the requirements of the Quality Management System
- The potential consequences of departure from specified procedures

#### 2. Responsibilities

Project Managers are responsible for ensuring that appropriate training is carried out and that all staff involved in their projects are aware of the requirements, rules and procedures to which they are to conform and against which they will be audited.

The Quality Manager is responsible for providing internal training in the QMS.

#### 3. Implementation

QP 10 - Training.

### 6.3 Infrastructure (ISO 9001:2000 - 6.3)

#### 1. Bitworks policy and objectives

Bitworks shall determine, provide and maintain the infrastructure to achieve product requirements regarding (but not limited to) the following:

- Workspace and associated facilities
- Hardware and Software
- Tools and Equipment
- Communication Facilities
- Supporting Services

#### 2. Responsibilities

The Partnership Secretary has overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

- QP 5 Quality Management System Review
- SP 3 Budget and Finance
- SP 6 Audits.

### 6.4 Work environment (ISO 9001:2000 - 6.4)

#### 1. Bitworks policy and objectives

Bitworks shall define and manage those human and physical factors of the work environment needed to achieve conformity of product.

This shall include:

- Health and safety conditions
- Work methods
- Work ethics
- Ambient working conditions

### 2. Responsibilities

Project Managers have overall responsibility for establishing, implementing and maintaining this activity.

**3. Implementation** Bitworks relevant project documents.

### 7 PRODUCT REALISATION (ISO 9001:2000 - 7)

### 7.1 Planning of realisation processes (ISO 9000:2000 - 7.1)

### 1. Bitworks policy and objectives

Processes that are necessary to realise the required product and their sequence and interaction shall be determined, planned and implemented taking into consideration the outputs from quality planning (see 5.4.2).

Bitworks shall ensure these processes are operated under controlled conditions and produce outputs, which meet customer requirements. Bitworks shall determine how each process affects the ability to meet product requirements and shall:

- Establish methods and practices relevant to these processes, to the extent necessary, to achieve consistent operation
- Determine and implement the criteria and methods to control processes, to the extent necessary, to achieve product conformity with the customer requirements
- Verify and validate that processes can be operated to achieve product conformity with customer requirements
- Determine and implement arrangements for measurement, monitoring and follow-up actions, to ensure processes continue to operate to achieve planned results and outputs (see 8)
- Ensure the availability of the information and data necessary to support the effective operation and monitoring of the processes
- Maintain as quality records the results of process control measures, to provide evidence of effective operation and monitoring of the processes (see 4.2.4)

### 2. Responsibilities

Bitworks Management has overall responsibility for establishing, implementing and maintaining this activity.

### 3. Implementation

- CP 1 Core Business Process
- SP 1 Human Resources
- SP 2 Quality
- SP 3 Budget and Finance
- SP 4 Corrective and Preventive Action
- SP 5 Documentation
- SP 6 Audits

### 7.2 Customer-related processes (ISO 9000:2000 - 7.2)

## 7.2.1 Determination of requirements related to the product (ISO 9001:2000 - 7.2.1)

### 1. Bitworks policy and objectives

Bitworks shall establish a process for identifying customer requirements that determine the:

- Completeness of the customer' s product and/or service requirements
- Requirements not specified by the customer but necessary for fitness for purpose

- Statutory, regulatory and legal requirements
- Customer requirements for availability, delivery and support of product and/or service

### 2. Responsibilities

The Senior Partners, assisted by the Project Managers, has overall responsibility for establishing, implementing and maintaining this activity.

### 3. Implementation

CP 1 - Core Business Process QP 6 - Customer Feedback

## 7.2.2 Review of requirements related to the product (ISO 9000:2000 - 7.2.2)

### 1. Bitworks policy and objectives

The customer requirements, including any requested changes, shall be reviewed before a commitment to supply a product is provided to the customer (e.g. submission of a tender, acceptance of a contract or order).

This Contract Review will ensure that:

- Customer requirements are clearly defined for product and/or service
- Where the customer provides no written statement of requirement, the customer requirements are confirmed before acceptance
- Contract or order requirements differing from those previously expressed, (e.g. in a tender or quotation), are resolved
- Bitworks has the ability to meet the customer requirements for the product and/or service

The results of the review and subsequent follow-up actions shall be recorded (see 4.2.4) and the information disseminated to all the relevant personnel.

#### 2. Responsibilities

Project Managers have overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

CP 1 - Core Business Process SP 5 - Documentation

### 7.2.3 Customer communication (ISO 9000:2000 - 7.2.3)

### 1. Bitworks policy and objectives

Bitworks shall determine and implement arrangements for customer communication with the overall aim of meeting customer requirements. Bitworks shall define communication requirements relating to:

- Product information
- Enquiries and order handling, including amendments
- Customer complaints and actions relating to non-conforming product (see 8.3 and 8.5.2)
- Customer responses relating to product performance (see 7.3.2 and 8.2.1)

### 2. Responsibilities

The Senior Partners has overall responsibility for establishing, implementing and maintaining this activity.

### 3. Implementation

- CP 1 Core Business Process
- SP 4 Corrective and Preventive Action
- **QP 6 Customer Feedback**

### 7.3 Design and development (ISO 9000:2000 - 7.3)

### 7.3.1 Design and development planning (ISO 9001:2000 - 7.3.1)

### 1. Bitworks policy and objectives

Bitworks plan and control the design and development of a product which shall include:

- Stages of the design and development process
- · Required review, verification and validation activities
- Responsibilities and authorities for design and development activities

Interfaces between different groups involved in design and development shall be managed to ensure effective communication and clarity of responsibilities.

Planning output shall be updated, as the design and development progresses.

#### 2. Responsibilities

Project Managers have overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

- CP 1 Core Business Process
- SP 4 Corrective and Preventive Action
- SP 5 Documentation
- SP 6 Audits

### 7.3.2 Design and development inputs (ISO 9001:2000 7.3.2)

#### 1. Bitworks policy and objectives

Bitworks shall define and record the requirements to be met by the product and/or service (see 4.2.4). These shall include:

- Functional and performance requirements from customer or market
- · Applicable statutory, regulatory and legal requirements
- Applicable environmental requirements
- Requirements derived from previous similar designs
- Any other requirements essential for design and development

These inputs shall be reviewed for adequacy and incomplete, ambiguous or conflicting requirements shall be resolved.

### 2. Responsibilities

Project Managers have overall responsibility for establishing, implementing and maintaining this activity.

### 3. Implementation

- CP 1 Core Business Process
- SP 4 Corrective and Preventive Action
- SP 5 Documentation
- SP 6 Audits

### 7.3.3 Design and development outputs (ISO 9001:2000 - 7.3.3)

### 1. Bitworks policy and objectives

Design and development output shall:

- Meet the design and development input requirements
- Contain or make reference to product and/or service acceptance criteria
- Define the characteristics of the product that are essential to its safe and proper use
- Be approved before being released

#### 2. Responsibilities

Project Managers have overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

- CP 1 Core Business Process
- SP 4 Corrective and Preventive Action
- SP 5 Documentation
- SP 6 Audits

### 7.3.4 Design and development review (ISO 9001:2000 - 7.3.4)

#### 1. Bitworks policy and objectives

At suitable stages, systematic reviews of design and development shall be conducted to:

- Evaluate the ability of a product to fulfil requirements for quality
- Identify problems
- Propose follow-up actions

Participants of these reviews shall include representatives of functions concerned with the design stage being reviewed.

Results of the reviews and subsequent follow-up actions shall be recorded (see 4.2.4).

#### 2. Responsibilities

Project Managers has overall responsibility for establishing, implementing and maintaining this activity.

35

### 3. Implementation

- CP 1 Core Business Process
- SP 4 Corrective and Preventive Action
- SP 5 Documentation
- SP 6 Audits.

### 7.3.5 Design and development verification (ISO 9001:2000 - 7.3.5)

### 1. Bitworks policy and objectives

A verification process shall be planned and implemented to ensure that the design and development output meets the design and development input. The results of the verification and subsequent follow-up actions shall be recorded (see 4.2.4).

### 2. Responsibilities

Project Managers have overall responsibility for establishing, implementing and maintaining this activity.

### 3. Implementation

- CP 1 Core Business Process
- SP 4 Corrective and Preventive Action
- SP 5 Documentation
- SP 6 Audits

### 7.3.6 Design and development validation (ISO 9001:2000 - 7.3.6)

#### 1. Bitworks policy and objectives

Prior to the delivery or implementation of the product and/or service, design and development validation shall be performed to confirm that resultant product and/or service is capable of meeting the particular requirements for a specific intended customer use.

Wherever applicable, validation shall be defined, planned and completed prior to the delivery or implementation of the product and/or service. Where it is impossible to undertake full validation prior to delivery or implementation, partial validation of the design or development outputs shall be undertaken to the maximum extent practical.

The results of the validation and subsequent follow-up actions shall be recorded (see 4.2.4).

#### 2. Responsibilities

Project Managers have overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

- CP 1 Core Business Process
- SP 4 Corrective and Preventive Action
- SP 5 Documentation
- SP 6 Audits
## 7.3.7 Control of design and development changes (ISO 9001:2000 - 7.3.7)

#### 1. Bitworks policy and objectives

Bitworks shall identify, document and control all design and development changes, and shall evaluate the effect of these changes and/or medications on:

- The interaction between the elements of the design and development
- The interaction between the component parts of the resulting product and/or service
- Existing products and/or services and upon post delivery product operations
- The need for carrying out re-verification or re-validation for all or part of the design and development outputs

The results of the review of changes and subsequent follow-up actions shall be recorded (see 4.2.4).

#### 2. Responsibilities

Project Managers have overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

- CP 1 Core Business Process
- SP 4 Corrective and Preventive Action
- SP 5 Documentation
- SP 6 Audits

## 7.4 Purchasing (ISO 9001:2000 - 7.4)

#### 7.4.1 Purchasing process (ISO 9001:2000 - 7.4.1)

#### 1. Bitworks policy and objectives

Although the majority of direct purchases only concern stationery and the maintenance/improvement of IT facilities, Bitworks, nevertheless, needs to control its purchasing processes to ensure that the purchased product conforms to Bitworks requirements. The type and extent of methods to control these processes shall be dependent on the effect of the purchased product upon the final product.

Bitworks shall evaluate and select suppliers based on their ability to supply products in accordance with Bitworks requirements. Evaluation, re-evaluation and selection criteria for suppliers shall be established. The results of evaluations and subsequent follow-up actions shall be recorded (see 4.2.4).

The Bitworks system for control of all purchased goods or subcontracted services shall ensure those products or services purchased and received conform to specified requirements and include provision for the assessment of suppliers and subcontractors. It shall also establish rules for the specification of requirements for purchased documents and the verification of goods and services received.

#### 2. Responsibilities

The Partnership Secretary, (assisted by the Project Managers and the Quality Manager), has overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

Individual (i.e. sectional) sub-contract assessment procedures according to product and/or contract.

### 7.4.2 Purchasing information (ISO 9001:2000 - 7.4.2)

#### 1. Bitworks policy and objectives

Purchasing documents shall contain information clearly describing the product and/or service ordered, including where appropriate:

- Requirements for approval or qualification of product and/or service, procedures, processes, equipment and personnel
- Any QMS requirements

Bitworks shall ensure the adequacy of specified purchase requirements prior to release.

#### 2. Responsibilities

The Partnership Secretary, (assisted by the Project Managers and the Quality Manager), has overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

Individual (i.e. sectional) sub-contract assessment procedures according to product and/or contract.

#### 7.4.3 Verification of purchased product (ISO 9001:2000 - 7.4.3)

#### 1. Bitworks policy and objectives

Bitworks shall determine and implement the procedures necessary for verification of purchased product (see 8.2.4).

Where Bitworks or its customer proposes to perform verification activities at the supplier's premises, Bitworks shall specify the required verification arrangements and method of product release in the purchasing documents.

#### 2. Responsibilities

The Partnership Secretary, (assisted by the Project Manager and the Quality Manager), has overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

Through individual sub-contract assessment by the Project Manager assisted by the Quality Manager according to product and/or contract.

## 7.5 Production and service provision (ISO 9001:2000 - 7.5)

#### 7.5.1 Control of production and service provision (ISO 9001:2000 - 7.5.1)

#### 1. Bitworks policy and objectives

Bitworks shall plan and control production and service operations, including those undertaken after initial delivery, through:

- The availability of information and specifications that clearly define the characteristics of the product that is to be achieved
- The availability of work instructions for those activities where they are necessary for the achievement of conformity of products
- The use and maintenance of suitable production, installation, and maintenance equipment (see 6.3)
- The availability of monitoring and measuring equipment
- The implementation of suitable monitoring and measuring activities (see 8.2.3 and 8.2.4)
- Suitable methods for release and delivery and/or installation of product and/or service

Bitworks management, assisted by Project Managers, has overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

Bitworks QMS Part 3 - Quality Procedures Bitworks QMS Part 4 - Work Instructions SP 1 - Human Resources SP 5 - Documentation

## 7.5.2 Validation of processes for production and service provision (ISO 9001:2000 - 7.5.2)

#### 1. Bitworks policy and objectives

Bitworks shall have procedures for validating the processes for production and service provision following the objectives of continual improvement:

- Review of documented processes, procedures and work instructions
- Assessment of production, installation, servicing equipment, and working environment
- Monitoring of process parameters
- Approval of processes and equipment

#### 1. Responsibilities

Bitworks management, assisted by Project Managers, has overall responsibility for establishing, implementing and maintaining this activity.

#### 2. Implementation

- SP 2 Quality
- SP 4 Corrective and Preventive Action
- SP 5 Documentation
- SP 6 Audits

#### 7.5.3 Identification and traceability (ISO 9001:2000 - 7.5.3)

#### 3. Bitworks policy and objectives

Bitworks shall have procedures for identifying the status of a product with respect to required measurement and verification activities and, where traceability is a requirement, Bitworks shall identify the product throughout all processes. In particular this shall apply to the component parts of the product where their interaction affects conformity with requirements.

Bitworks management, assisted by Project Managers, has overall responsibility for establishing, implementing and maintaining this activity.

For Software Projects the Project Manager is responsible for recording the test results against the product baseline together with traceability back to the customer requirements and/or product specification to customer requirements as appropriate.

#### 5. Implementation

SP 5 - Documentation SP 6 – Audits WI 1 – Software Engineering

#### 7.5.4 Customer property (ISO 9001:2000 - 7.5.4)

#### 1. Bitworks policy and objectives

Bitworks shall ensure that all customer property while it is under Bitworks supervision or being used by Bitworks is identified, verified, stored and maintained Any customer property that is lost, damaged or otherwise found to be unsuitable for use shall be recorded and reported to the customer (see 7.2.3).

NOTE: Customer property may include intellectual property e.g. information provided in confidence.

#### 2. Responsibilities

Bitworks management, assisted by Project Managers, has overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

SP 5 - Documentation

#### 7.5.5 Preservation of product (ISO 9001:2000 - 7.5.5)

#### 1. Bitworks policy and objectives

Bitworks shall ensure that during internal processing and final delivery of product to the intended destination that the identification, packaging, storage, preservation, and handling do not affect conformity with product requirements. This shall also apply to parts or components of a product and elements of a service.

Product release/delivery shall not proceed until all the specified activities have been satisfactorily completed and the related documentation is available and authorised.

#### 2. Responsibilities

The Partnership Secretary, assisted by Project Managers, has overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

Bitworks QMS Part 3 - Quality Procedures Bitworks QMS Part 4 - Work Instructions SP5 - Documentation

# 7.6 Control of monitoring and measuring devices (ISO 9001:2000 - 7.6)

#### 1. Bitworks policy and objectives

Bitworks shall ensure that documented procedures to control the calibration and maintenance of inspection, measuring and test equipment which is used to demonstrate the conformance of the product to the specified requirements. Inspection, measuring and test equipment shall be used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement requirement.

#### 4. Responsibilities

The Project Manager has overall responsibility for establishing, implementing and maintaining this activity.

For Software Projects the 'Equipment and Measurement Requirements & Configuration' and the 'Equipment Table with Calibration Status' are recorded in the project 'one document' prior to any formal testing.

#### 5. Implementation

Bitworks QMS Part 3 - Quality Procedures Bitworks QMS Part 4 – WI 1 Software Engineering - Software Test and Verification SP5 - Documentation

# 8 MEASUREMENT, ANALYSIS AND IMPROVEMENT (ISO 9001:2000 - 8)

## 8.1 General (ISO 9001:2000 - 8.1)

#### 1. Bitworks policy and objectives

Bitworks shall define, plan and implement measurement, monitoring, analysis and improvement processes to ensure that the QMS, processes and products conform to requirements and shall ensure that:

- The type, location, timing and frequency of measurements and the requirements for records are defined (see 4.2.4)
- The effectiveness of measures implemented is periodically evaluated

Bitworks shall identify and use appropriate statistical tools and the results of data analysis and improvement activities shall be an input to the management review process (see 5.6).

#### 2. Responsibilities

Bitworks management, assisted by Project Managers, has overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

SP 5 - Documentation SP 6 - Audits

## 8.2 Monitoring and measurement (ISO 9001:2000 - 8.2)

## 8.2.1 Customer satisfaction (ISO 9001:2000 - 8.2.1)

#### 1. Bitworks policy and objectives

Bitworks shall monitor information on customer satisfaction and/or dissatisfaction as one of the measurements of performance of the QMS. The methods and measures for obtaining and utilising such information and data shall be defined.

#### 2. Responsibilities

Bitworks management, assisted by Project Managers, has overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

SP 4 - Corrective and Preventive Action

## 8.2.2 Internal audit (ISO 9001:2000 - 8.2.2)

#### 1. Bitworks policy and objectives

Bitworks shall carry out objective audits in order to determine if QMS has been effectively implemented and maintained and conforms to ISO 9001:2000. In addition, Bitworks may carry out audits to identify potential opportunities for improvement.

The audit process, including the schedule, shall be based on the status and importance of the activities and/or areas to be audited and the results of previous audits.

42

NOTE: See also ISO 10011 Parts 1, 2 and 3 for guidance.

#### 2. Responsibilities

Bitworks management has overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

SP 6 - Audits

#### 8.2.3 Monitoring and measurement of processes (ISO 9001:2000 - 8.2.3)

#### 1. Bitworks policy and objectives

Bitworks shall monitor and measure processes to ensure that they continue to satisfy their intended purpose.

#### 2. Responsibilities

Bitworks management, assisted by Project Managers, has overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

SP 6 - Audits

#### 8.2.4 Monitoring and measurement of product (ISO 9001:2000 - 8.2.4)

#### 1. Bitworks policy and objectives

Bitworks shall monitor and measure the characteristics of the product to verify that requirements for the product and/or service are met.

Evidence conformance shall be documented and recorded. Records shall indicate the authority responsible for release of product (see 4.2.4).

#### 2. Responsibilities

Bitworks management, assisted by Project Managers, has overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

SP 6 - Audits

## 8.3 Control of non-conforming product (ISO 9001:2000 - 8.3)

#### 1. Bitworks policy and objectives

Bitworks shall ensure that products that do not conform to requirements are identified and controlled to prevent unintended use or delivery. These non-conformities shall be:

- · Corrected or adjusted to conform to requirements and re-validated, or
- Accepted under concession, with or without correction or adjustment, or
- Re-assigned for alternative valid application, or
- Rejected as unsuitable

The Quality Manager, assisted by the Project Managers, has overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

SP 4 - Corrective and Preventive Action SP 6 - Audits

## 8.4 Analysis of data (ISO 9001:2000 - 8.4)

#### 1. Bitworks policy and objectives

Bitworks shall analyse all applicable data to determine the suitability, adequacy and effectiveness of the QMS and use this to provide information relating to:

- · Customer satisfaction and/or dissatisfaction
- Conformance to product requirements
- Characteristics of trends and opportunities for preventive action
- Suppliers

#### 2. Responsibilities

Bitworks management, assisted by the Project Managers, has overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

SP 4 - Corrective and Preventive Action SP 6 - Audits

## 8.5 Improvement (ISO 9001:2000 - 8.5)

#### 8.5.1 Continual improvement (ISO 9001:2000 - 8.5.1)

#### 1. Bitworks policy and objectives

Bitworks shall plan and manage the processes necessary for the continual improvement of the QMS through the use of a system level procedure that describes the use of quality policy, objectives, internal audit results, analysis of data, corrective and preventive action and management review to facilitate continual improvement.

#### 2. Responsibilities

Bitworks management has overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

SP 4 - Corrective and Preventive Action SP 6 - Audits

#### 8.5.2 Corrective action (ISO 9001:2000 - 8.5.2)

#### 1. Bitworks policy and objectives

Bitworks shall define the requirements for:

• Identifying non-conformities (including customer complaints)

- Determination of the causes of non-conformity
- · Evaluating the need for actions to ensure that non-conformities do not recur
- Implementing corrective action
- Recording the results of actions taken
- Reviewing that corrective action taken is effective and recorded

Bitworks management, assisted by the Project Managers, has overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

SP 4 - Corrective and Preventive Action SP 6 - Audits

#### 8.5.3 Preventive action (ISO 9001:2000 - 8.5.3)

#### 1. Bitworks policy and objectives

Bitworks shall define the requirements for:

- · Identification of potential non-conformities
- Determination of the causes of the identified potential non-conformities
- Determination of preventive action needed to eliminate causes of potential nonconformities
- Implementation of preventive action
- Recording the results of action taken
- Reviewing that preventive action taken is effective

#### 2. Responsibilities

Bitworks management, assisted by Project Managers, has overall responsibility for establishing, implementing and maintaining this activity.

#### 3. Implementation

SP 4 - Corrective and Preventive Action SP 6 - Audits

## Annex A - Bitworks organisation and responsibilities



#### Figure 4: Bitworks Design & Consultancy - organisational chart

#### 1. Senior Partners

The Senior Partners are responsible for the overall management of Bitworks. They are responsible for the overall and final success of all contracts undertaken, for providing guidance on all major issues and for ensuring that all Bitworks products and services are produced and delivered to the highest possible level.

The Senior Partners are responsible for:

- Supervising the day to day running of Bitworks
- The overall progress of the work with which he has been entrusted and the budget placed at his disposal
- Controlling budget, time schedules, Quality Plans, resources and quality within the company
- Approving changes to agreed time schedules, resources and budgets
- Ensuring that the organisation will, at all times, meet the business requirements and objectives (as stipulated in Bitworks Memorandum of Articles and Association) as well as keeping to the agreed time schedule
- Maintaining overall responsibility for all projects
- Preparing contracts, in consultation with Project Managers

#### 2. Quality Manager

The Quality Manager is responsible for ensuring that the organisation's QMS is defined, implemented, audited and monitored in order to ensure that Bitworks documents and procedures comply with the customers' quality standards as well as the ISO 9000 series of documents concerning "Quality Management System". The Quality Manager shall report directly to the Senior Partners.

Her/His tasks shall include:

- Maintenance and effectiveness of the company QMS
- Ensuring compliance of the company QMS with ISO 9001:2000
- Ensuring the consistency of the company QMS

• Ensuring that the quality message is transmitted to and understood by everyone

#### 3. Partnership Secretary

The Bitworks Administration, Finance and Secretarial Office is headed by the Partnership Secretary. The Partnership Secretary is responsible for activities such as publishing the QMS Documents on the Bitworks Website distribution of Bitworks general documents as well as aspects of financial and contractual administration. The Partnership Secretary shall report directly to the Senior Partners.

His tasks shall include:

- Issuing financial reports;
- Producing financial statements to the Senior Partners
- The organisation of special meetings, workshops, seminars etc. when requested to do so by the Senior Partners
- Arranging (and planning) publication of documents to the Website or otherwise when required

#### 4. Project Managers

Project Managers are appointed by the Senior Partners and are responsible for the delivery of a Project, the budget placed at their disposal, for organising the work of their project and distributing this work between the project staff according to the directives, procedures and instructions making up the Bitworks QMS whilst duly observing the requirements of Bitworks Memorandum of Articles and Association.

Project Managers shall report directly to the Senior Partners and their tasks shall include:

- Responsibility for the general progress of the work of their project and the management of their authorised budget;
- Controlling the time schedules, work packages, resources and quality of the tasks allocated to their project
- Ensuring that the project will, at all times, meet the objectives of the customer and the business needs of Bitworks
- Directing the studies of the project with the constant aim of achieving an accelerated and sustained tempo of the project within the scope of their own particular Quality Plan and individual work packages
- The progress and time management of all project sub-tasks.

#### 5. Project Staff

Project Staff shall carry out the accepted tasks assigned by their Project Manager, within the deadlines set.

#### 6. Subcontractors and Consultants

When the work/studies of a project falls outside the scope of the project team, the Senior Partners may authorise the temporary co-operation of subcontractors and consultants.

A contract/agreement for the subcontractor's or consultant's participation will be concluded with his company or with his parent company by the Partnership Secretary.

The subcontractor or consultant shall be expected to make use of his personal knowledge and experience acquired both in and outside his company without, however, in any way committing the latter. The company who provides subcontractors or consultants shall, in return, grant them the greatest possible freedom of action and initiative and shall afford them the time and facilities required to carry out whatever work/studies they might be charged with in their capacity as a member of an Bitworks Project Team.

Clause No	ISO 9001:2000 Title	Process	Quality Manual
4	Quality Management System		
4.1	General requirements		
4.2	Documentation requirements		All
4.2.1	General		
4.2.2	Quality Manual	QP 5	
4.2.3	Control of documents	QP 1	
4.2.4	Control of quality records	SP 5, QP 5	
5	Management responsibility		
5.1	Management commitment		Sections 5-8
5.2	Customer focus		All
5.3	Quality policy		1.5
5.4	Planning		
5.4.1	Quality objectives		Section 1.5
5.4.2	Quality management system planning		Sections 1.5, 2.1 & 2.2
5.5	Responsibility, authority and communication		
5.5.1	General		Section 2
5.5.2	Responsibility and authority		Annex A
5.5.3	Management representative		Annex A
5.5.4	Internal communication	QP 10	
5.6	Management review		
5.6.1	General	QP 5	
5.6.2	Review input	QP 5	
5.6.3	Review output	QP 5	
6	Resource management		
6.1	Provision of resources	SP 1, SP 3	
6.2	Human resources		
6.2.1	General	SP 1	
6.2.2	Competence, awareness and training	QP 10	
6.3	Infrastructure	SP 3, SP 6, QP 5	
6.4	Work environment		HSE documents
7	Product realisation		
7.1	Planning of realisation processes	CP 1, SP 1, SP 2, SP 3, SP 4, SP 5, SP 6	
7.2	Customer-related processes		
7.2.1	Determination of requirements related to the product	CP 1, QP 6	
7.2.2	Review of requirements related to the product	SP 5	
7.2.3	Customer communications	SP 4	

## Annex B - ISO 9001:2000 cross-check

7.3.1 Design and development planning CP 1, SP 4, SP   7.3.2 Design and development inputs CP 1, SP 4, SP   7.3.3 Design and development outputs CP 1, SP 4, SP   7.3.4 Design and development review CP 1, SP 4, SP   7.3.5 Design and development verification CP 1, SP 4, SP   7.3.6 Design and development verification CP 1, SP 4, SP   7.3.6 Design and development verification CP 1, SP 4, SP   7.3.7 Control of design and development changes CP 1, SP 4, SP   7.4 Purchasing CP 1, SP 4, SP   7.4.1 Purchasing process Subcontractor assessment procedures   7.4.2 Purchasing information Subcontractor assessment procedures   7.4.3 Verification of purchased product Subcontractor assessment procedures   7.5.4 Purchasing information Subcontractor assessment procedures   7.5.5 Preservation of production and service provision SP 1 Part 3, Part 4   7.5.4 Customer property SP 5 Part 3, Part 4   7.5.5 Preservation of product SP 5, SP 6 [S 1, SP 6]   7.5.4 Customer satisf	7.3	Design and development		
7.3.3Design and development outputsCP 1, SP 4, SP 5, SP 67.3.4Design and development reviewCP 1, SP 4, SP 5, SP 67.3.5Design and development verificationCP 1, SP 4, SP 5, SP 67.3.6Design and development validationCP 1, SP 4, SP 5, SP 67.3.7Control of design and development changesCP 1, SP 4, SP 5, SP 67.4Purchasing7.4.1Purchasing processSubcontractor assessment procedures7.4.2Purchasing informationSubcontractor assessment procedures7.5.3Production and service provisionSP 17.5.1Control of process for production and service provisionSP 17.5.2Validation of processes for production and service provisionSP 17.5.4Customer propertySP 57.5.5Preservation of productSP 57.5.6Preservation of productSP 57.5.7Preservation of productSP 57.5.8Monitoring and measurement8.1GeneralSP 5, SP 68.2Monitoring and measurement of processesSP 68.2.3Monitoring and measurement of productSP 68.2.4Monitoring and measurement of productSP 68.3Control of non-conforming productSP 68.4Analysis of dataSP 68.5.1Control of non-conforming productSP 4, SP 68.5.1Control of non-conforming productSP 68.5.1Control of non-conforming productSP 4, SP 6 <td>7.3.1</td> <td>Design and development planning</td> <td></td>	7.3.1	Design and development planning		
5, SP 67.3.4Design and development reviewCP 1, SP 4, SP 5, SP 67.3.5Design and development verificationCP 1, SP 4, SP 5, SP 67.3.6Design and development validationCP 1, SP 4, SP 5, SP 67.3.7Control of design and development changesCP 1, SP 4, SP 5, SP 67.4PurchasingCP 1, SP 4, SP 5, SP 67.4.1Purchasing processSubcontractor assessment procedures7.4.2Purchasing informationSubcontractor assessment procedures7.4.3Verification of purchased productSubcontractor assessment procedures7.5.4Porduction and service provisionSP 17.5.5Preduction and service provisionSP 5, SP 67.5.4Customer propertySP 57.5.5Preservation of productSP 57.5.6Preservation of productSP 57.5.7Preservation of productSP 57.5.8Measurement, analysis and improvement8.1GeneralSP 5, SP 68.2Monitoring and measurement of processesSP 68.2.1Customer satisfactionSP 4, QP 68.2.2Internal auditSP 68.3.2Control of neasurement of productSP 68.4.4Analysis of dataSP 4, SP 68.5.1Control of nonconforming productSP 68.5.2Corrective actionSP 4, SP 6	7.3.2	Design and development inputs		
5. SP 67.3.5Design and development verificationCP 1, SP 4, SP 5, SP 67.3.6Design and development validationCP 1, SP 4, SP 5, SP 67.3.7Control of design and development changesCP 1, SP 4, SP 5, SP 67.4Purchasing7.4.1Purchasing processSubcontractor assessment procedures7.4.2Purchasing informationSubcontractor assessment procedures7.4.3Verification of purchased productSubcontractor assessment procedures7.5Production and service provisionSP 17.5.1Control of production and service provisionSP 17.5.2Validation of processes for production and service provisionSP 5, SP 67.5.3Identification and traceabilitySP 5, SP 67.5.4Customer propertySP 57.5.5Preservation of productSP 5, SP 67.6Control of measuring and monitoring devices8Measurement, analysis and improvementSP 5, SP 68.2Monitoring and measurement of processesSP 68.2.1Customer satisfactionSP 4, QP 68.2.2Internal auditSP 68.2.3Monitoring and measurement of processesSP 68.4.4Analysis of dataSP 4, SP 68.5.1Control of nonconforming productSP 68.5.1Control of nonconforming productSP 68.5.1Control of nonconforming productSP 68.5.2Corrective actionSP 4, SP 6	7.3.3	Design and development outputs		
A. Second Seco	7.3.4	Design and development review		
5, SP 67.3.7Control of design and development changesCP 1, SP 4, SP 5, SP 67.4Purchasing7.4.1Purchasing processSubcontractor assessment procedures7.4.2Purchasing informationSubcontractor assessment procedures7.4.3Verification of purchased productSubcontractor assessment procedures7.5Production and service provisionSP 17.5.1Control of production and service provisionSP 17.5.2Validation of processes for production and service provisionSP 57.5.4Customer propertySP 57.5.5Preservation of productSP 57.6Control of measuring and monitoring devicesSP 5, SP 68Measurement, analysis and improvementSP 6, SP 68.1GeneralSP 6, SP 68.2Monitoring and measurement of processesSP 68.2.1Customer satisfactionSP 68.2.2Internal auditSP 68.3.2Control of non-conforming productSP 68.4.4Analysis of dataSP 4, SP 68.5.1Control of non-conforming productSP 4, SP 68.5.2Corrective actionSP 4, SP 6	7.3.5	Design and development verification		
7.4Purchasing7.4.1Purchasing processSubcontractor assessment procedures7.4.2Purchasing informationSubcontractor assessment procedures7.4.3Verification of purchased productSubcontractor assessment procedures7.5.1Production and service provisionSP 17.5.2Validation of processes for production and service provisionSP 5, SP 67.5.3Identification and traceabilitySP 5, SP 67.5.4Customer propertySP 57.5.5Preservation of productSP 57.5.6Control of measuring and monitoring devicesSP 5, SP 68Measurement, analysis and improvementSP 5, SP 68.2Monitoring and measurementSP 5, SP 68.2.1Customer satisfactionSP 4, QP 68.2.2Internal auditSP 68.2.3Monitoring and measurement of productSP 68.2.4Monitoring and measurement of productSP 68.3Control of non-conforming productSP 68.4.4Analysis of dataSP 4, SP 68.5ImprovementSP 4, SP 68.5.1Contrul improvementSP 4, SP 68.5.2Corrective actionSP 4, SP 6	7.3.6	Design and development validation		
7.4.1Purchasing processSubcontractor assessment procedures7.4.2Purchasing informationSubcontractor assessment procedures7.4.3Verification of purchased productSubcontractor assessment procedures7.5.1Production and service provisionSP 1Part 3, Part 47.5.2Validation of processes for production and service provisionSP 5Part 3, Part 47.5.3Identification and traceabilitySP 5, SP 67.5.4Customer propertySP 5Part 3, Part 47.5.5Preservation of productSP 5Part 3, Part 47.6Control of measuring and monitoring devicesSP 5, SP 68Measurement, analysis and improvementSP 5, SP 68.2Monitoring and measurementSP 5, SP 68.2.1Customer satisfactionSP 4, QP 68.2.2Internal auditSP 68.2.3Monitoring and measurement of productSP 68.2.4Monitoring and measurement of productSP 68.3Control of non-conforming productSP 4, SP 68.4.4Analysis of dataSP 4, SP 68.5ImprovementSP 4, SP 68.5.1Continual improvementSP 4, SP 68.5.2Corrective actionSP 4, SP 6	7.3.7	Control of design and development changes		
7.4.2Purchasing informationSubcontractor assessment procedures7.4.3Verification of purchased productSubcontractor assessment procedures7.5Production and service provisionSP 1Part 3, Part 47.5.1Control of production and service provisionSP 1Part 3, Part 47.5.2Validation of processes for production and service provisionSP 5, SP 67.5.3Identification and traceabilitySP 5, SP 67.5.4Customer propertySP 5Part 3, Part 47.5.5Preservation of productSP 5Part 3, Part 47.6Control of measuring and monitoring devicesSP 5, SP 68Measurement, analysis and improvementSP 5, SP 68.2Monitoring and measurementSP 4, QP 68.2.1Customer satisfactionSP 68.2.2Internal auditSP 68.2.3Monitoring and measurement of processesSP 68.2.4Monitoring and measurement of productSP 68.3Control of non-conforming productSP 4, SP 68.4Analysis of dataSP 4, SP 68.5ImprovementSP 4, SP 68.5.1Continual improvementSP 4, SP 68.5.2Corrective actionSP 4, SP 6	7.4	Purchasing		
7.4.3Verification of purchased productSubcontractor assessment procedures7.5Production and service provisionSP 1Part 3, Part 47.5.1Control of production and service provisionSP 1Part 3, Part 47.5.2Validation of processes for production and service provisionSP 57.5.3Identification and traceabilitySP 5, SP 67.5.4Customer propertySP 57.5.5Preservation of productSP 5Part 3, Part 47.6Control of measuring and monitoring devicesSP 5, SP 68Measurement, analysis and improvementSP 5, SP 68.2Monitoring and measurementSP 5, SP 68.2.1Customer satisfactionSP 4, QP 68.2.2Internal auditSP 68.2.3Monitoring and measurement of productSP 68.2.4Monitoring and measurement of productSP 68.3Control of non-conforming productSP 4, SP 68.4Analysis of dataSP 4, SP 68.5ImprovementSP 4, SP 68.5.1Continual improvementSP 4, SP 68.5.2Corrective actionSP 4, SP 6	7.4.1	Purchasing process	Subcontractor assessment procedures	
7.5Production and service provisionSP 1Part 3, Part 47.5.1Control of production and service provisionSP 1Part 3, Part 47.5.2Validation of processes for production and service provisionSP 5, SP 67.5.3Identification and traceabilitySP 5, SP 67.5.4Customer propertySP 57.5.5Preservation of productSP 57.6Control of measuring and monitoring devicesSP 5, SP 68Measurement, analysis and improvementSP 5, SP 68.2Monitoring and measurementSP 5, SP 68.2.1Customer satisfactionSP 4, QP 68.2.2Internal auditSP 68.2.3Monitoring and measurement of processesSP 68.2.4Monitoring and measurement of productSP 68.3Control of no-conforming productSP 4, SP 68.4Analysis of dataSP 4, SP 68.5ImprovementSP 4, SP 68.5.1Continual improvementSP 4, SP 68.5.2Corrective actionSP 4, SP 6	7.4.2	Purchasing information	Subcontractor assessment procedures	
7.5.1Control of production and service provisionSP 1Part 3, Part 47.5.2Validation of processes for production and service provisionSP 57.5.3Identification and traceabilitySP 5, SP 67.5.4Customer propertySP 5Part 3, Part 47.5.5Preservation of productSP 5Part 3, Part 47.6Control of measuring and monitoring devicesSP 5, SP 68Measurement, analysis and improvementSP 5, SP 68.1GeneralSP 5, SP 68.2Monitoring and measurementSP 4, QP 68.2.1Customer satisfactionSP 4, QP 68.2.2Internal auditSP 68.2.3Monitoring and measurement of processesSP 68.2.4Monitoring and measurement of productSP 68.3Control of non-conforming productSP 4, SP 68.4Analysis of dataSP 4, SP 68.5ImprovementSP 4, SP 68.5.1Continual improvementSP 4, SP 68.5.2Corrective actionSP 4, SP 6	7.4.3	Verification of purchased product	Subcontractor assessment procedures	
7.5.2Validation of processes for production and service provisionSP 5, SP 67.5.3Identification and traceabilitySP 5, SP 67.5.4Customer propertySP 57.5.5Preservation of productSP 57.6Control of measuring and monitoring devicesSP 5, SP 68Measurement, analysis and improvement8.1GeneralSP 5, SP 68.2Monitoring and measurement8.2.1Customer satisfactionSP 4, QP 68.2.2Internal auditSP 68.2.3Monitoring and measurement of processesSP 68.2.4Monitoring and measurement of productSP 68.3Control of non-conforming productSP 4, SP 68.4Analysis of dataSP 4, SP 68.5ImprovementSP 4, SP 68.5.1Contriual improvementSP 4, SP 68.5.2Corrective actionSP 4, SP 6	7.5	Production and service provision		
service provisionSP 5, SP 67.5.3Identification and traceabilitySP 5, SP 67.5.4Customer propertySP 57.5.5Preservation of productSP 57.6Control of measuring and monitoring devicesSP 5, SP 68Measurement, analysis and improvementSP 5, SP 68.1GeneralSP 5, SP 68.2Monitoring and measurementSP 4, QP 68.2.1Customer satisfactionSP 4, QP 68.2.2Internal auditSP 68.2.3Monitoring and measurement of processesSP 68.2.4Monitoring and measurement of productSP 68.3Control of non-conforming productSP 4, SP 68.4Analysis of dataSP 4, SP 68.5ImprovementSP 4, SP 68.5.1Control autiinprovementSP 4, SP 68.5.2Corrective actionSP 4, SP 6	7.5.1	Control of production and service provision	SP 1 Part 3, Part 4	
7.5.4Customer propertySP 57.5.5Preservation of productSP 5Part 3, Part 47.6Control of measuring and monitoring devicesSP 5Part 3, Part 48Measurement, analysis and improvementSP 5, SP 68.1GeneralSP 5, SP 68.2Monitoring and measurementSP 4, QP 68.2.1Customer satisfactionSP 4, QP 68.2.2Internal auditSP 68.2.3Monitoring and measurement of processesSP 68.2.4Monitoring and measurement of productSP 68.3Control of non-conforming productSP 4, SP 68.4Analysis of dataSP 4, SP 68.5ImprovementSP 4, SP 68.5.1Continual improvementSP 4, SP 68.5.2Corrective actionSP 4, SP 6	7.5.2			
7.5.5Preservation of productSP 5Part 3, Part 47.6Control of measuring and monitoring devicesSP 5Part 3, Part 48Measurement, analysis and improvementSP 5, SP 68.1GeneralSP 5, SP 68.2Monitoring and measurementSP 4, QP 68.2.1Customer satisfactionSP 68.2.2Internal auditSP 68.2.3Monitoring and measurement of processesSP 68.2.4Monitoring and measurement of productSP 4, SP 68.3Control of non-conforming productSP 4, SP 68.4Analysis of dataSP 4, SP 68.5ImprovementSP 4, SP 68.5.1Continual improvementSP 4, SP 68.5.2Corrective actionSP 4, SP 6	7.5.3	Identification and traceability	SP 5, SP 6	
7.6Control of measuring and monitoring devices8Measurement, analysis and improvement8.1General8.2Monitoring and measurement8.2.1Customer satisfaction8.2.2Internal audit8.2.3Monitoring and measurement of processes8.2.4Monitoring and measurement of product8.3Control of non-conforming product8.4Analysis of data8.5Improvement8.5.1Continual improvement8.5.2Corrective action8.5.2Corrective action	7.5.4	Customer property	SP 5	
devices8Measurement, analysis and improvement8.1GeneralSP 5, SP 68.2Monitoring and measurement8.2.1Customer satisfactionSP 4, QP 68.2.2Internal auditSP 68.2.3Monitoring and measurement of processesSP 68.2.4Monitoring and measurement of productSP 68.3Control of non-conforming productSP 4, SP 68.4Analysis of dataSP 4, SP 68.5ImprovementSP 4, SP 68.5.1Continual improvementSP 4, SP 68.5.2Corrective actionSP 4, SP 6	7.5.5	Preservation of product	SP 5 Part 3, Part 4	
8.1GeneralSP 5, SP 68.2Monitoring and measurement8.2.1Customer satisfactionSP 4, QP 68.2.2Internal auditSP 68.2.3Monitoring and measurement of processesSP 68.2.4Monitoring and measurement of productSP 68.3Control of non-conforming productSP 4, SP 68.4Analysis of dataSP 4, SP 68.5ImprovementSP 4, SP 68.5.1Continual improvementSP 4, SP 68.5.2Corrective actionSP 4, SP 6	7.6	<b>a a</b>		
8.2Monitoring and measurement8.2.1Customer satisfactionSP 4, QP 68.2.2Internal auditSP 68.2.3Monitoring and measurement of processesSP 68.2.4Monitoring and measurement of productSP 68.3Control of non-conforming productSP 4, SP 68.4Analysis of dataSP 4, SP 68.5ImprovementSP 4, SP 68.5.1Continual improvementSP 4, SP 68.5.2Corrective actionSP 4, SP 6	8	Measurement, analysis and improvement		
8.2.1Customer satisfactionSP 4, QP 68.2.2Internal auditSP 68.2.3Monitoring and measurement of processesSP 68.2.4Monitoring and measurement of productSP 68.3Control of non-conforming productSP 4, SP 68.4Analysis of dataSP 4, SP 68.5ImprovementSP 4, SP 68.5.1Continual improvementSP 4, SP 68.5.2Corrective actionSP 4, SP 6	8.1	General	SP 5, SP 6	
8.2.2Internal auditSP 68.2.3Monitoring and measurement of processesSP 68.2.4Monitoring and measurement of productSP 68.3Control of non-conforming productSP 4, SP 68.4Analysis of dataSP 4, SP 68.5ImprovementSP 4, SP 68.5.1Continual improvementSP 4, SP 68.5.2Corrective actionSP 4, SP 6	8.2	Monitoring and measurement		
8.2.3Monitoring and measurement of processesSP 68.2.4Monitoring and measurement of productSP 68.3Control of non-conforming productSP 4, SP 68.4Analysis of dataSP 4, SP 68.5ImprovementSP 4, SP 68.5.1Continual improvementSP 4, SP 68.5.2Corrective actionSP 4, SP 6	8.2.1	Customer satisfaction	SP 4, QP 6	
8.2.4Monitoring and measurement of productSP 68.3Control of non-conforming productSP 4, SP 68.4Analysis of dataSP 4, SP 68.5Improvement8.5.1Continual improvementSP 4, SP 68.5.2Corrective actionSP 4, SP 6	8.2.2	Internal audit	SP 6	
8.3Control of non-conforming productSP 4, SP 68.4Analysis of dataSP 4, SP 68.5Improvement8.5.1Continual improvementSP 4, SP 68.5.2Corrective actionSP 4, SP 6	8.2.3	Monitoring and measurement of processes	SP 6	
8.4Analysis of dataSP 4, SP 68.5Improvement8.5.1Continual improvement8.5.2Corrective actionSP 4, SP 6	8.2.4	Monitoring and measurement of product	SP 6	
8.5Improvement8.5.1Continual improvementSP 4, SP 68.5.2Corrective actionSP 4, SP 6	8.3	Control of non-conforming product	SP 4, SP 6	
8.5.1Continual improvementSP 4, SP 68.5.2Corrective actionSP 4, SP 6	8.4	Analysis of data	SP 4, SP 6	
8.5.2 Corrective action SP 4, SP 6	8.5	Improvement		
8.5.2 Corrective action SP 4, SP 6	8.5.1	Continual improvement	SP 4, SP 6	
8.5.3 Preventative action SP 4, SP 6	8.5.2	Corrective action	SP 4, SP 6	
	8.5.3	Preventative action	SP 4, SP 6	