

Audit Committee 16 March 2011

Benefits of HPC's Quality Management System

Executive summary and recommendations

Introduction

HPC has had a registration with ISO 9001 Quality Management Standard externally audited by BSI since July 2004. (ISO9001:2000).

HPC migrated to the new standard ISO9001:2008 in April at the first available opportunity. The new standard requires that we monitor suppliers more closely, including auditing them at their own site if required.

HPC have audited the external Archive company, our major Renewals Printer, our scanning and printing bureau.

We will be extending out our external audit function in 2011-12.

Decision

Audit Committee is invited to discuss the report attached below.

Background information

Resource implications

Included in annual departmental work plans.

Financial implications

Included in annual departmental work plans.

Appendices

Appendix.1 Sample process – Customer service

Appendix 2. 2010 QMS amendments

Appendix 3 Overview of ISO9001 and World Wide take up

Date of paper

26 January 2011

Date	Ver.	Dept/Cmte	Doc Type	Title	Status	Int. Aud.
2011-01-18	a	QUA	RPT	Audit committee report - benefits of ISO9001 at HPC	Draft DD: None	Public RD: None

Benefits of HPC's Quality Management System

Audit committee has been receiving updates on the results of BSI audits of our Quality Management System since 2004.

ISO9001 is a process standard developed by the International Organization for Standardisation and accredited in the UK by the Quality Assurance Agency. HPC are audited to this standard by the British Standards Institute.

British Standards Institute publish the following high level extract on their website. (BSI are conducting research in an attempt to quantify benefits of ISO 9001 registration, and we have volunteered to take part.)

As customers become more sophisticated, better informed and hold higher expectations, the only way a business can survive and prosper is to offer a commitment to quality. In fact, any organization, whatever their size or industry sector, can give themselves a secure future by introducing a quality management system (QMS) such as [BS EN ISO 9001](#).

[BS EN ISO 9001:2008](#)

Quality management systems. Requirements

Maintaining a high level of customer satisfaction is a significant challenge for many organizations. One way of meeting this challenge is to put in place and use a customer satisfaction code of conduct. A customer satisfaction code of conduct consists of promises and related provisions that address issues such as product delivery, product returns, handling of personal information of customers, advertising and stipulations concerning particular attributes of a product or its performance.

HPC is not a commercial organisation, and does not have “customers” in the traditional sense, however HPC try to act as if we were a commercial organisation, where our registrants and stakeholders could go somewhere else if we failed to treat them with appropriate standards of quality and cost effectiveness. This means that we possibly try harder to achieve our goals, and maintain our standards of work, than if we could just hide behind a mask of regulatory legislation.

ISO9001 demands the following principles are adhered to;

1. Customer Focus
2. Leadership
3. Involvement of people
4. Process approach
5. System approach to MGMT
6. Continual improvement
7. Factual approach to decision making

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8. Mutually beneficial supplier relationships

ISO9001 provides a formal mechanism for the way we work at HPC. If the ISO standard did not exist, we would still choose to work under ISO type processes, as this is the most sensible and efficient way to work.

We would fix issues occurring, (Corrective action) and then remodel processes to stop the event happening again (Preventive Action).

This is a rational approach to limit disruption, reduce the cost of rework. and the reduce impact on stakeholders.

[If one was to get a flat tyre every time one drove out of ones drive due to going through a spill of nails, one would sweep up the nails, rather than change the tyre each time.]

ISO9001 is a process standard, not a product or service standard. It is about how we do things, rather than what we produce or how many.

The 9001 Store carried out research in 2008

US publicly held companies on the NYSE with ISO 9001 quality standard show significant improvement in financial performance compared to those without the standard.

Source: <http://www.manufacturingnews.com/news/02/0830/art1.html>

- 30% Reduction in customer claims
- 95% improvement in delivery time
- Reduced defects from 3% to 0.5%
- 40% reduction in product cycle time.
- 20% increase in on-time delivery
- International acceptance and recognition
- Facilitated trade in international markets
- Promoting of safety, reliability and quality in food products.

The Results of Certification to ISO 9001

- Well defined and documented procedures improve the consistency of output.
- Quality is constantly measured
- Procedures ensure corrective action is taken whenever defects occur.
- Defect rates decrease
- Defects are caught earlier and are corrected at a lower cost.
- Defining procedures identifies current practices that are obsolete or inefficient.
- Documented procedures are easier for new employees to follow.
- Organizations retain or increase market share, increasing sales or revenues.

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- Independently verified adherence to the standard

HPC are not a commercial organisation, but our reputation can be damaged in a similar way if we did not fix and prevent recurrence of quality related issues.

In the commercial sector a product recall for a major car manufacturer impacts the bottom line via direct costs to implement the fix, and harms the reputation of the manufacturer probably impacting future sales. We do not have sales to loose, but we do have a reputation.

One of our Top Ten Risks (Risk 1.5) is Loss of Reputation. The first mitigation is **Quality of operational procedures**

This quality is maintained by our use of ISO9001

Example of ISO 9001 training in the new employee induction.

What is ISO 9001:2008?



ISO 9001:2008 (Quality Management System) Standard is a set of guidelines that deliver;



Cost / Benefit?

There is a relatively small cost for each external audit (£1000) and an annual management fee for being on the BSI register (£700). As additional standards are adopted at HPC there will be an increase in the cost of auditing, and some additional training costs, which includes CPD type elements for those internally managing the ISO 27001 and BS25999 standards.

The QMS (and future Information Security Management System ISMS) is managed on a day to day basis by the Business Process Improvement team, part of the Operations Directorate. All members undertake other tasks, including supporting the reporting functions, archiving, business analysis, ad-hoc project work, security, risk and business continuity.

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Three persons are trained to carry out internal audits up to ISO9001 standard, Tom Berrie (TB) (Information Services Manager), Cherise Evans (CE) (PA to the Director of Operations) and Roy Dunn (RD) (Head of Business Process Improvement). Currently RD is also trained to Lead audit and develop ISO27001 (Information Security standards).

It is a key principle of the ISO standard that one does not audit ones own work, thus the reason for multiple auditors.

For instance CE manages the internal Customer Service tracking process on a day to day basis, so any Customer Service audit is carried out by TB or RD.

Thus the internal audit effort is split between three employees, and relates to approximately 2/3 FTE.

The cost of not having ISO9001 in place is very difficult to quantify in financial terms. Other regulators that have lost Chief Executives or Chairs have not had ISO9001 in place. These organisations seem to have had recurring issues that built into such a volume that government have become aware of issues not being resolved in a timely manner, and have been compelled to act.

ISO9001 demands “Corrective” and “Preventive” action processes to address any issues, and ultimately fix the cause of the issue.

HPC rigorously apply corrective and preventive actions, where process owners are required to address any issues impacting processes. The BPI department assist with process redesign in light of the issues raised. However, the processes remain under the ownership of the appropriate section of the business.

High level Requirements for ISO9001

1. Determine how to manage “quality management” in the organisation
2. Develop a Quality Manual plus a quality policy and objectives
3. Resource Management in response to workload and automation
4. Measurement of quality and defects
5. Control of product design

The external audit process.

Over a three year BSI audit cycle, all operational parts of the business are audited, but not always in a traditional department by department sense.

For instance Partners working for HPC, and the processes in recruiting, training, and monitoring them were audited under a “suppliers” audit.

ISO have a requirement that auditors do not work on a single client continuously for more that 6 years (2 cycles of registration), to ensure a certain amount of independence is maintained. ISO audit generally looks at

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processes, and adherence to those processes, rather than simply counting output.

The internal audit process.

Generally HPC’s internal QMS audit predicts those audits by BSI, sometimes with a dry run for those process owners not audited before, plus a follow up audit.

An internal audit cycle is proposed for each financial year, and published to the intranet, however we remain flexible to ensure we do not interrupt the business at very inconvenient times. We do however insist on audits taking place. They cannot be put off indefinitely.

Some departments use an internal audit to help crystallize ideas and build new processes. The Registrations department took this approach when developing the internal aspects of running multi-profession concurrent CPD audits.

BPI have also been involved in developing the enhanced checking of international applicants identity, and developing scan to web assessment processes for the registrations department.

Process mapping standards.

HPC BPI do not impose strict design control on style of QMS documentation, to ensure the users of the processes understand their own processes where ever possible. It would not be effective to impose design or layout requirements if process users could not understand them.

In the past some departmental processes have been word documents, or tables of prescribed activities. However we favour “swim lane” diagrams where possible, and this would be HPC standard if we were to adopt documentation standards.

Some HPC departments have developed complete new sets of ISO9001 compatible process documentation (IT department), and the BPI department simply makes them live on the QMS, and audits against them.

HPC’s key IT suppliers work from swim lane diagrams where totally new processes are developed (e.g. CPD).

Support for Internal users if required.

Internal Business Analysis training materials have been developed by RD to assist those working in this area. These have previously been shared with the Project Management team. Where we have external Business Analysts working on our behalf, they are generally working to very similar documentation standards as those we use ourselves, where given free rein.

As HPC develop new processes or amend existing processes, we automatically develop Business Process diagrams to ISEB standards (maintained by the British Computer Society).

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Other regulators in the Health arena are investigating ISO9001 registration, or have adopted ISO standards (NMC & GMC). HPC's CHRE review has used our ISO registration as a mitigation for not using Key Performance Indicators.

Whilst any organisation is full of good intentions, maintaining a process map set for the entire organisation is time consuming, and could slow down development in disorganised companies. At HPC we document new ideas as processes as they are developed. It is a principle that nothing important is put in place at HPC unless it is "ISO'ed"

Promotion of ISO9001 at HPC

The 2009 HPC wide training day centred around ISO9001, and various audits and assistance is used to promote the methodology at a low level. It is important not to over sell such standards usage as this can turn people off the idea very easily. The BPI department aim for a subtle reinforcement when ever possible.

All new employees attend a BPI induction which includes highlights on ISO9001 and how it is used at HPC.

Globally "World ISO Standards day" is celebrated every October 14th but has yet to be used as a promotional opportunity at HPC!

Specific examples of where ISO9001 has benefited HPC include the following;

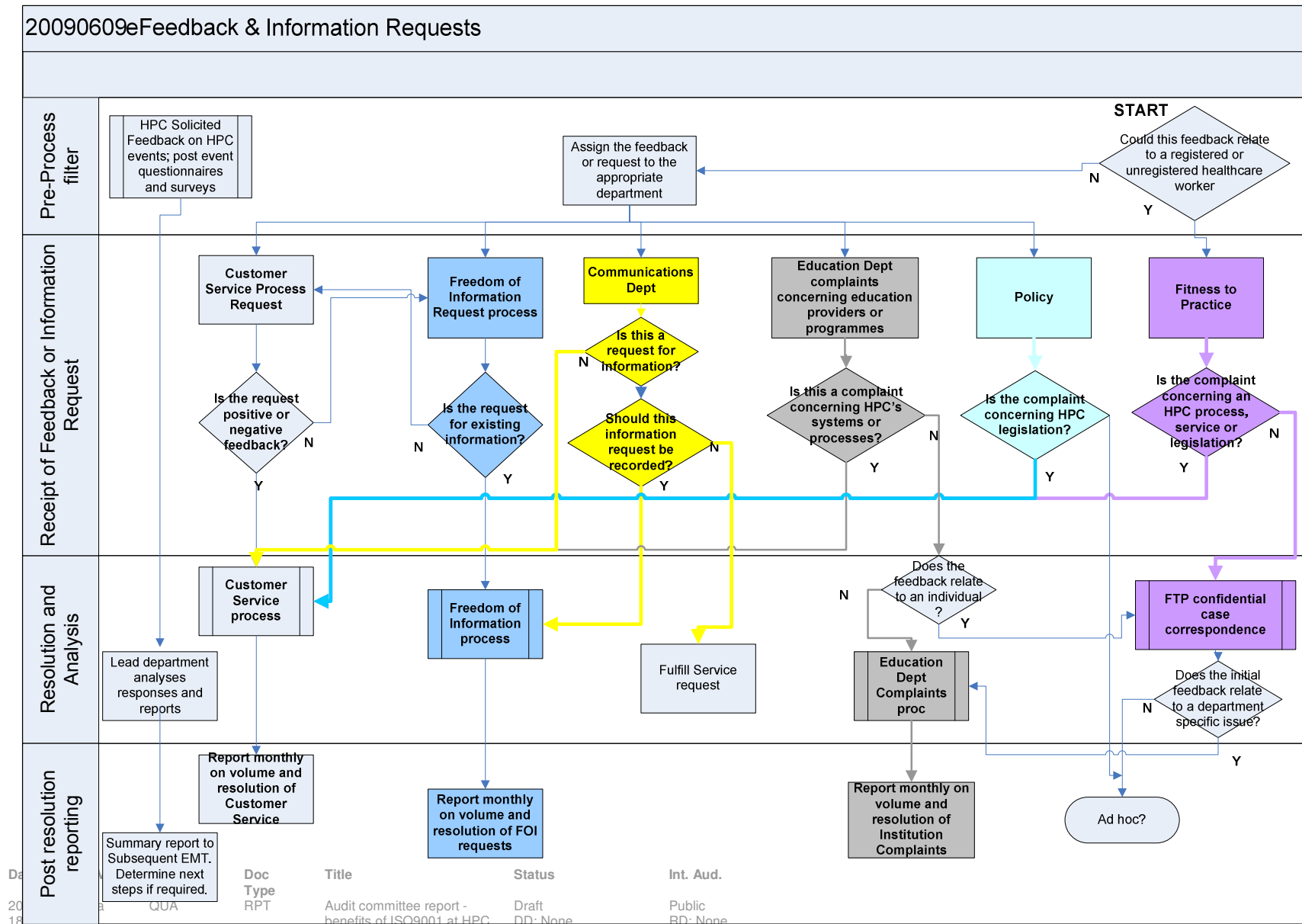
- Predicting workload bottle necks in the Partner Assessment workload,
- Changing the content of returned renewal notice packs for registrants to avoid damage to ICR renewal forms on their resubmission to HPC
- Having sufficiently detailed instructions to operate non departmental office machinery for other departments
- Enhancing the relevant parts of Communications processes to cope with high impact events that could damage HPC's reputation.
- Improving security of outbound items for Registration Assessors.
- Finding improved employee performance assessment tracking methods.
- Improving archived item tracking
- Document control process, and convention

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- Integration of Risk management techniques with HPC's QMS Management Review (Monthly EMT)

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Appendix.1 Sample process – Customer service



Appendix 2. 2010 QMS amendments

The table below records modifications to HPC's Quality Management System in year 2010 (not FY). It does not record completely new processes. These are recorded in another part of the document control process.

QMS updated	Nature of update on QMS
04/01/2010	/ - Update Customer service
01/04/2010	/ - Addition of Hearing Aid Dispensers as 15 th profession
27/05/2010	Management Review 0020006/0003 - Document inclusion of Preventive & Corrective Action and detailed analysis of Customer feedback
28/05/2010	Record control 0020010/0003 - Record changes to how the Document Control is maintained following migration to a new QMS IT System.
01/06/2010	Quality Management Processes Quality Manual 0020001/0005 - Added overview diagram of ISO9001 at HPC
03/06/2010	About this section 0020011/0002 - Update to include mention of changed navigation following technology change.
03/06/2010	Feedback form 0020013/0003 - Update for Notes email use from Note DB. No longer FrontPage/Notes function
04/06/2010	Control Parameters - Business Process Improvement 0050140/0002 - QMS add BPI dept
04/06/2010	Business Process Improvement 0040063/0001 - Put BPI processes into one overview page
04/06/2010	1.0 Initial contact 0030145/0002 - QMS UPDATE
04/06/2010	2.0 Assessment 0030147/0001 - QMS UPDATE
04/06/2010	2.0 Assessment 0030147/0002 - QMS UPDATE
04/06/2010	3.0 Investigation 0030148/0002 - QMS UPDATE
04/06/2010	ISO 9001 overview 0040065/0001 - QMS update
04/06/2010	4.0 Observation 0030149/0002 - QMS UPDATE
04/06/2010	5.0 ICP 0030150/0002 - QMS UPDATE
04/06/2010	6.0 Public hearing 0030151/0002 - qms update
04/06/2010	7.0 Restoration hearing 0030152/0002 - QMS UPDATE
04/06/2010	8.0 Interim order 0030153/0002 - QMS UPDATE

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04/06/2010 9.0 Protection of title 0030154/0002 - QMS UPDATE

04/06/2010 Summary Preventive & Corrective Action 0040066/0001 - QMS update

04/06/2010 10.0 Health and character application declaration 0030155/0002 - QMS UPDATE

04/06/2010 11.0 Registration appeals 0030156/0002 - QMS UPDATE

04/06/2010 12.0 Mediation 0030157/0002 - QMS UPDATE

04/06/2010 13.0 Retention 0030158/0002 - QMS UPDATE

04/06/2010 14.0 Misc cases 0030159/0002 - QMS UPDATE

04/06/2010 15.0 Archiving 0030160/0002 - QMS UPDATE

04/06/2010 Customer Service & Feedback Process 0040067/0001 - QMS update

04/06/2010 Collation of Monthly Management Reports 0040068/0001 - QMS update

04/06/2010 Archiving processes - Generic 0040069/0001 - Move archive supplier from Recall to Deepstore. Create generic archive instructions.

04/06/2010 Secretariat processes 0030050/0009 - QMS UPDATE

04/06/2010 Batch Process Scheduler Fail Safe 0030161/0001 - QMS Update - on live process

04/06/2010 Registrations Process Timing Changes 0030162/0001 - QMS Update - existing process

04/06/2010 Secretariat - Council member complaints investigation 0030140/0002 - QMS UPDATE

04/06/2010 Batch Process Scheduler Fail Safe 0030162/0001 - QMS update

04/06/2010 Registration Process Timing Changes 0030161/0001 - QMS update existing process

07/06/2010 Council Annual Meeting 0030164/0002 - QMS UPDATE

07/06/2010 Supporting Council Members' role 0030165/0002 - QMS UPDATE

07/06/2010 Servicing to council and committee 0030071/0004 - QMS UPDATE

07/06/2010 Committees appointments process 0030051/0002 - QMS UPDATE

07/06/2010 Council away day 0030084/0002 - QMS UPDATE

07/06/2010 Council members and non-council members competency-based appraisal 0030053/0005 - QMS UPDATE

07/06/2010 Appointment of non-council members to committees 0030052/0002 - QMS UPDATE

07/06/2010 15.0 Archiving 0030160/0003 - QMS update - new archive company

07/06/2010 Election of Committee Chairs 0030142/0003 - QMS UPDATE

07/06/2010 Council away day 0030084/0003 - QMS UPDATE

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07/06/2010 Appointment of non-council members to committees 0030052/0003 - QMS UPDATE

09/06/2010 Quality Management Processes ISO9001 0020000/0003 - Include latest proposed BSI audit schedule

15/06/2010 BSI Audit Reports to ISO9001 0020014/0001 - First published new set

29/06/2010 Business Continuity - Crisis Management 0040071/0002 - Update to latest draft version based on JL (Dir of Comms) feedback.

09/07/2010 CPD 0030096/0002 - Slight modification at req of Hd of Reg, apply scanning step at Pass or Reject post assessment stage.

15/07/2010 Policy processes 0030080/0007 - Added link to enhanced document legal sign off proc

22/07/2010 Quality Management System -Business processes 0010004/0006 - Change to the "FeedBack" form link

04/08/2010 Publications Process 0030168/0001 - Modified at request of Marc Seale.

06/08/2010 Control Parameters - Education 0050020/0007 - Update of information as a result of internal audit 5/8/2010

18/08/2010 Information Technology processes 0040007/0008 - Roll out IT2010 processes

31/08/2010 Control Parameters - Human Resources & partners 0050060/0003 - Updates provided by T Haskins, HR Director 26/08/2010 via email

31/08/2010 Human Resources processes 0040020/0007 - Update HR dept overview at request of HR Director

07/09/2010 UK Applications 0030041/0006 - Minor modifications to reflect current processes being refined (eg DD forms to Finance after scanning) Signed off by James Wilson

08/09/2010 ICR renewals 0030096/0002 - Modification to ICR process following software upgrade.

08/09/2010 Quality control 0030098/0002 - Update checking processes to allow for shift and rota and task changes over time for each reg advisor

08/09/2010 Standard batch renewal reminders 0030096/0002 - Update following change to new core renewal printing company

10/09/2010 Partner recruitment 0040045/0006 - Process updated request by HR Partner Manager

10/09/2010 Update contact details 0040062/0002 - Process updated requested by HR Partner Manager.

10/09/2010 Partner training 0040047/0004 - Process update as requested by the HR Partner Manager.

10/09/2010 Registrations - Weekly certificates 0030169/0001 - Updated to reflect new printer and change to process

13/09/2010 Employee relations 0040061/0004 - Updated to include diagram for Employees Consultation Group

13/09/2010 Archiving 0030102/0002 - A consolidated view of application archiving processes across the three application routes has been produced.

13/09/2010 Exit process 0040060/0005 - Updated at request of HR Director

13/09/2010 Employee sickness and absence management 0040027/0002 - Updated at request of HR Director

13/09/2010 Induction 0040022/0002 - Updated at request of HR Director

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13/09/2010 Performance management 0040023/0002 - Update process at request of HR Director

13/09/2010 Recruitment 0040021/0005 - Process updated at request of HR Director

13/09/2010 Remuneration 0040015/0003 - Updated at request of HR Director

13/09/2010 Training and development 0040024/0002 - Updated at request of HR Director

14/09/2010 Partner roles 0040044/0002 - QMS Update, requested by Partners Manager.

14/09/2010 Partner agreements 0040046/0002 - Process/QMS update requested by the Partners Manager.

14/09/2010 Legal Assessor, Registration Assessor, Visitor and CPD Assessor 0040152/0002 - Process Update requested by the Partners Manager

14/09/2010 Panel member and Panel Chair Agreements 0040153/0002 - Process / QMS update requested by the Partner Manager.

15/09/2010 Exit process - Employees and contractors 0040060/0006 - Review by HR team to update processes.

15/09/2010 Receipt of cash payments 0030127/0004 - Updated at request of Head of Reg in process refresh

16/09/2010 Receipt of credit card payments 0030092/0004 - Updated at the request of the TL/Head of Registrations

17/09/2010 Readmission 0030043/0007 - Updated at the request of CSM CH

20/09/2010 Batch Process Scheduler Fail Safe 0030162/0002 - Slight change to regularity of meetings to check between CSM & TL to check any changes. Now only as required by changing process timings.

21/09/2010 Exit process - Employees and contractors 0040060/0007 - Slight change to layout, no longer splitting out IT, Facilities - now all in one process. Finance remains separate.

07/10/2010 Exit process - Employees and contractors 0040060/0008 - Attempt to fix doc control by incrntg version - no changes

07/10/2010 Registration processes 0030040/0011 - Added in additional process link on diagram - Transit of docs

13/10/2010 Quality Management System -Business processes 0010004/0007 - Add new link for ISMS link for ISO27001:2005 adoption project

04/11/2010 Partner performance management 0040048/0004 - Update to process as requested by the Partner Manager.

04/11/2010 Partner training 0040047/0005 - AS REQUESTED BY THE PARTNER MANAGER

16/11/2010 Quality Management System -Business processes 0010004/0008 - Remove old back up suggestions link, as Feedback form is now working. rolled out fully to HPC after trial.

14/12/2010 BSI Audit Reports to ISO9001 0020014/0002 - Loaded latest BSI external report copy.

15/12/2010 Process Model 0040070/0002 - Add Tea making example to illustrate a process

15/12/2010 Quality Management Processes ISO9001 0020018/0004 - Add additional link to feedback form

15/12/2010 Update contact details 0040062/0003 - Updated as requested by the Partner Manager 15/12/2010

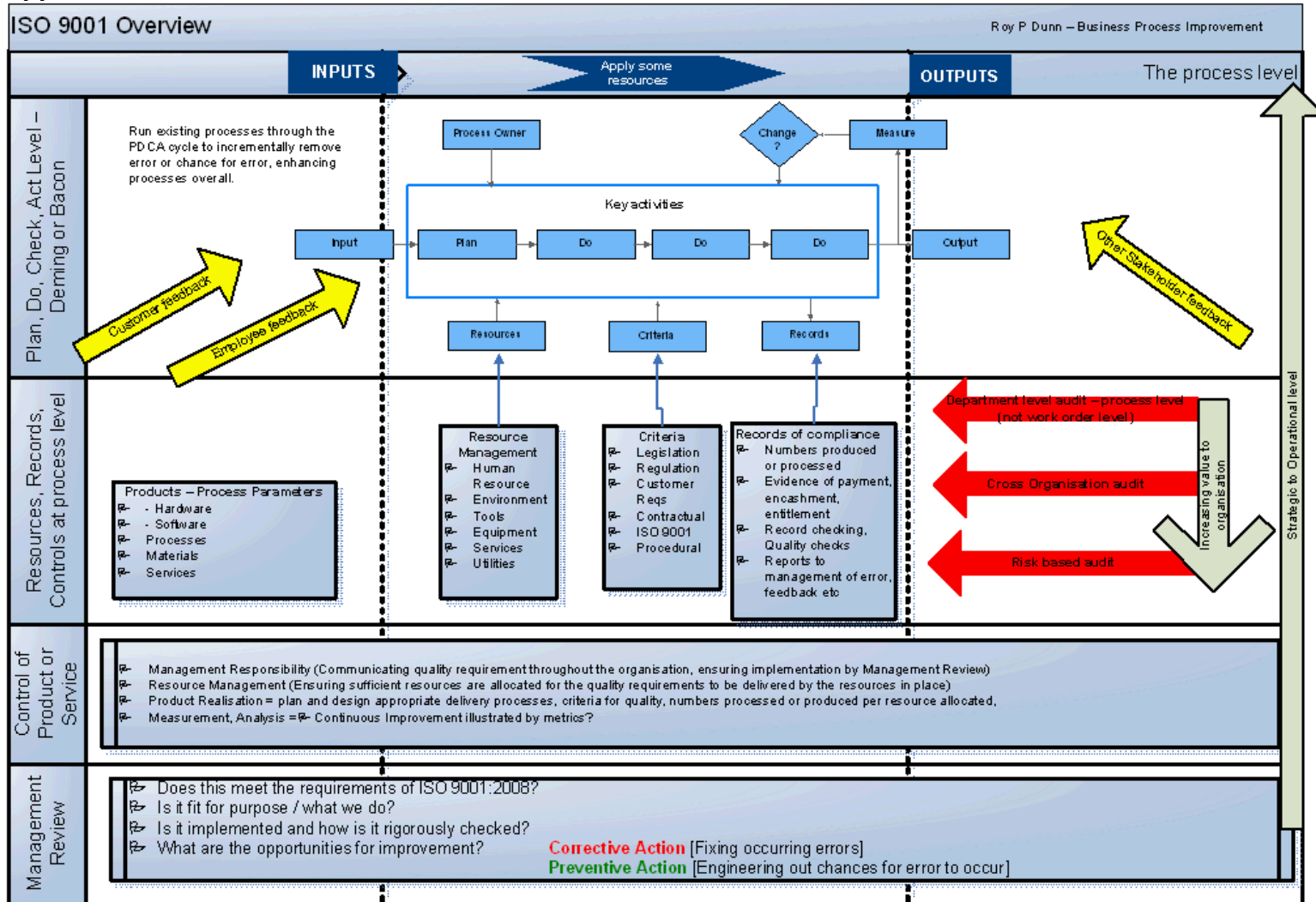
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15/12/2010 Registrant partner lapsing process 0040061/0002 - Updated as requested by the Partner Manager 15/12/2010

15/12/2010 Partner recruitment 0040045/0007 - Updated as requested by the Partner Manager 15/12/2010

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Appendix 3 Overview of ISO9001



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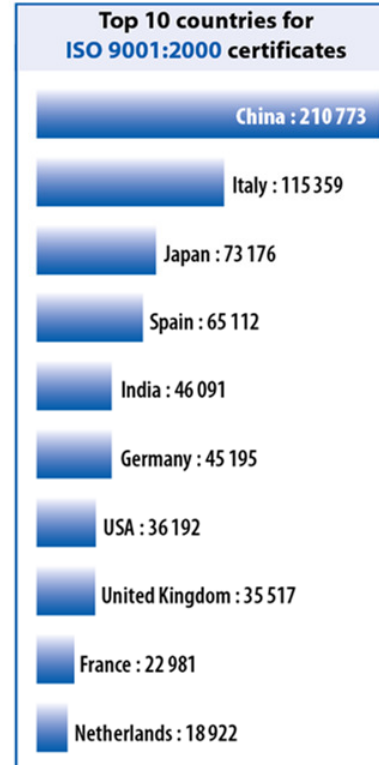
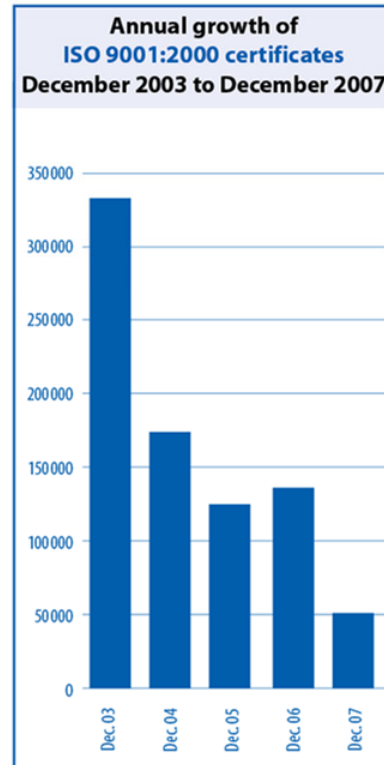
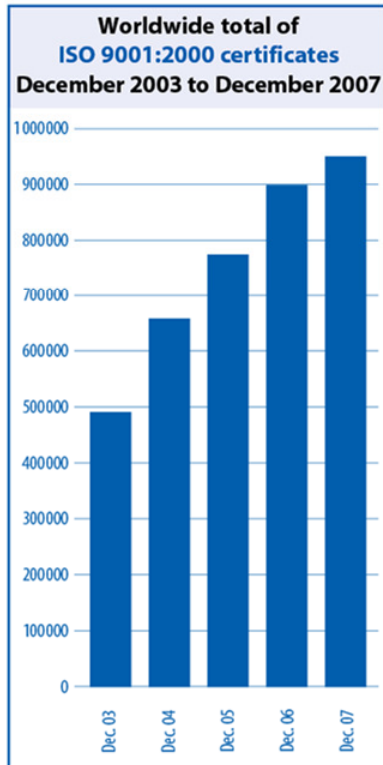
Take up of ISO9001:2000 up to 2009

Worldwide total of ISO 9001:2000/2008 certificates

Dec 2000	Dec 2001	Dec 2002	Dec 2003	Dec 2004	Dec 2005	Dec 2006	Dec 2007	Dec 2008	Dec 2009
457834	510349	561767	497919	660132	773867	896929	951486	982832	1064785

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The ISO Survey



FEATURES AND BENEFITS

ISO 9001 is by far the world's most established quality framework, setting the standard not just for quality management systems but for management systems in general. ISO 9001 is helping all kinds of organisations to succeed through improved customer satisfaction and staff motivation.

BUSINESS RISK	BUSINESS NEED	FEATURE OF STANDARD	ADVANTAGES (How will it help?)	BENEFITS (What's in it for my business?)
Loss of customers through variations in service, product or quality of output.	To ensure a consistent output and streamline operations and processes.	Requires one set of processes that are used throughout the organisation taking into account areas such as marketing, finance etc. These all play a part in the service offered to the client.	Requirements of the specific standards are coordinated. Workloads are streamlined. Duplication and bureaucracy are reduced. Systems in place for internal audits, document control, training and administration make the organisation more effective and efficient.	Gives management confidence that clients will receive what has been agreed. Increase in customer satisfaction. More management time for proactive measures.
Business stagnates and does not improve or evolve.	To improve business performance and ensure organisation is more competitive and dynamic.	Improves systems to ensure client receives what has been agreed in the contract. Improves effectiveness and efficiency of the organisation.	By constantly looking for improvements and having the systems in place an organisation is much better prepared for changes that need to be made.	Less time spent on correcting impacts on other areas. More management time for proactive measures. Able to deal with change more effectively.

For more information visit www.bsigroup.co.uk/Iso9001 or call 0845 080 9000

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ISO 9001 Quality Management

BUSINESS RISK	BUSINESS NEED	FEATURE OF STANDARD	ADVANTAGES (How will it help?)	BENEFITS (What's in it for my business?)
Low employee morale and client dissatisfaction.	A happy and informed workforce and client base.	Requires one set of objectives that are inline with the organisation's polices and customer feedback. Objectives are met by having planned processes in place.	A highly motivated workforce meaning greater customer satisfaction. Improvement in both internal and external communications.	Less time spent correcting mixed messages. More management time for continual improvement. Improved customer satisfaction, employee morale and motivation.
Non-compliance with regulatory requirements.	Confidence that regulatory requirements are met in the most effective way for the organisation and their stakeholders.	Requires all regulatory requirements to be met that are applicable to the organisation that are a consequence of the products and services that the organisation provides. These should be communicated to staff to ensure they are aware of the implications of the regulations.	Ensures the organisation and all staff are aware of and comply with all regulatory requirements.	Reduces time spent correcting any breaches. Allows time to be focused on winning new business. Protects business image and reputation.


For more information visit www.bsigroup.co.uk/iso9001 or call 0845 080 9000



The BSI certification mark can be used on your stationery, literature and vehicles when you have successfully achieved certification.

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