

PATENT COOPERATION TREATY (PCT)

Common Quality Framework for International Search and Preliminary Examination

INITIAL REPORT ON QUALITY MANAGEMENT SYSTEMS

prepared by EUROPEAN PATENT OFFICE

The Authority should provide general background information relevant to the quality management system (QMS) as set forth in this template.

The descriptions below each main heading of this template should be considered examples of the type and arrangement of information that should be included under each heading. Each Authority may provide additional information beyond that set forth in this template as desired.

INTRODUCTION (PARAGRAPHS 21.01 - 21.03)

If applicable, the Authority may at this point indicate any recognized normative reference or basis for their quality management system besides Chapter 21, such as ISO 9001, under the heading "Normative Reference for QMS"

For example: "Normative reference for QMS: ISO 9001, EQS (European Quality System)"

Each authority should then provide at least the information indicated in the descriptive boxes, under the following headings

The EPO aims to constantly improve its Quality Management System. To achieve this Principal Directorate Quality Management (PDQM) is mandated to realise the QMS. Results of all quality related activities e.g. Quality Audit, Operational Quality Control of examination work (CL-OQC), Patent Administration work (PA-OQC) etc. are fed to the Quality Board which advises top management on quality related matters.

Current activities are:

The MAC (Management Advisory Committee) of the EPO decided to proceed with a project to achieve ISO9001:2008 compliance. A project board was set up under the Prince2 project management methodology. The project initiation stage has commenced.

The office implemented MSP (Managing Successful Programmes) to ensure oversight and to avoid conflict of numerous programmes and projects running in parallel.

The EPO's Strategic Renewal Process (SRP) is an ongoing process to help make the Office fit for the challenges it is facing. This process is divided into different programmes and projects.

One activity under SRP is the IP5 programme launched by the five major Offices (EPO, USPTO, SIPO, KIPO and JPO) in May 2007. The vision of the IP5 programme is improved global co-operation so as to *eliminate unnecessary duplication of work among the IP5 Offices and to enhance patent examination efficiency and quality*. One of the ten foundation projects aims to provide Common Rules for Examination Practice and Quality Control. This project is led by SIPO.

A further SRP activity is "Raising the bar" (RTB). It focuses on internal practice, legal aspects and external practice. The latest development concerned proposals to amend Rules of PCT. At the 40th session of the Assembly of the PCT Union (PCT Assembly) held in Geneva between 22 September and 1 October 2009, approval was given to amendments to Rules 46.5 and 66.8 PCT as proposed by the EPO at the last Meeting of International Authorities. An additional SRP activity is "the Single Patent Process" (SPP). It focuses on the EPO's vision of the future and the implementation of a highly efficient patent process. It aims to ensure that the initiatives developed support quality assurance in the future including the integration of more plausibility checks in automated processes and supporting tools.

1. LEADERSHIP AND POLICY

21.04 Confirm that the following are clearly documented, and that this documentation is available internally:

- (a) The quality policy established by top management.
- (b) The roles and names of those bodies and individuals responsible for the QMS, as delegated by top management.
- (c) An organisational chart showing all those bodies and individuals responsible for the QMS.

(a)
The quality policy of the EPO is laid down in CA147/04.

(b)
Principal Directorate Quality Management (PDQM) is responsible for the QMS. Current post holder is Ms Milena Lonati. The Principal Directorate includes three directorates, as follows: The EPO's QMS is designed, implemented and maintained by Directorate Quality Management Support, currently headed by Mr Hubert Plugge. Directorate Practice and Procedure delivers comprehensive working standards for examiners and formalities staff, and is headed by Mr Mark Weaver. Directorate Metrics and Standards defines, evaluates and implements quality metrics and is headed by Mr James Pearce.

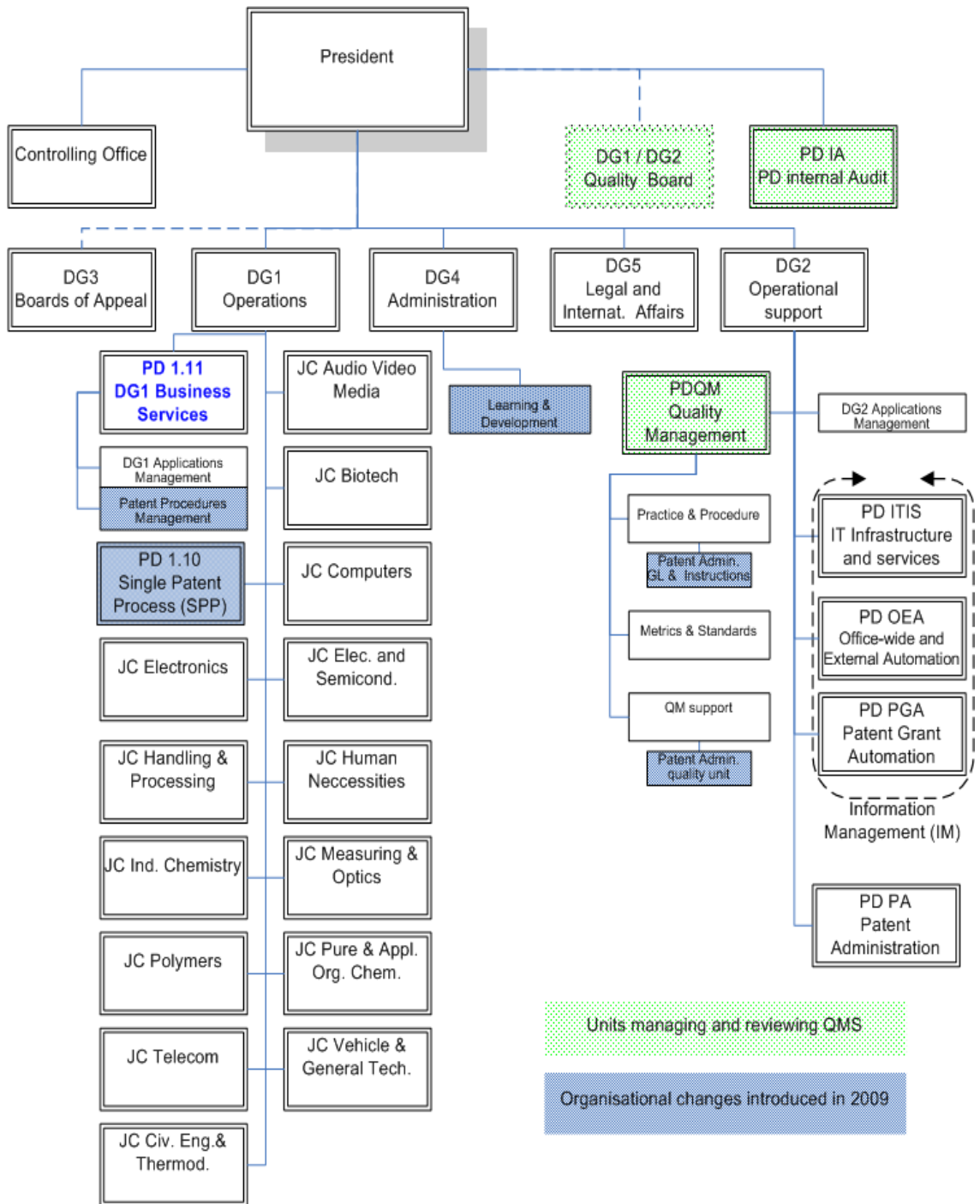
The body with overall responsibility for quality related issues is the Quality Board, consisting of the Principal director (PD) of PDQM, the PD of DG2- Patent administration and the PD-DG1 responsible for quality matters.

(c) Organisational changes in DG1 and DG2 enhancing provision and support of tools for search and examination work (S&E).

See organigram and comments below.

- The EPO centralised the relevant units responsible for developing and implementing a QMS by moving the quality unit PD Patent Administration to Directorate Quality Management Support in PD Quality Management (DG2).
- The EPO also centralised the departments responsible for establishing Guidelines and instructions to administrative staff by moving the relevant unit PD Patent Administration to the search and examination equivalent, Directorate Practice and Procedure in PD Quality Management.
- The EPO centralised its training departments under Principal Directorate Human Resources in DG4 in 2009.
- DG1 operations created a new directorate Patent Procedures Management which assures the maintenance of those procedures for which DG1 is responsible.

Organigram January 2010



21.05 Indicate (e.g. by means of a table) the extent of compatibility between the Authority's QMS and the requirements of Chapter 21 of these International Search and Preliminary Examination Guidelines. Alternatively, indicate where the Authority is not yet compliant with these requirements.

Chapter 21 requirement			Extent of compliance		
			full	part	no
21.04	(a)	Quality policy available	✓		
	(b)	Identified roles and names for QMS responsibility	✓		
	(c)	Organisational chart available	✓		
21.05		Established compatibility of QMS with Chapter 21	✓		
21.06	(a)	Mechanisms to ensure effectiveness of the QMS	✓		
	(b)	Control of the continual improvement process		✓	
21.07	(a)	Communication of management about this standard to staff	✓		
	(b)	The PCT Guidelines are in line with the Authority's QMS	✓		
21.08	(a)	Management reviews take place	✓		
	(b)	Quality objectives are reviewed	✓		
	(c)	Communication of quality objectives throughout the Authority	✓		
21.09	(a)	Performance of a yearly internal review of the QMS in/to	✓		
	(b)	(i) determine the extent to which the QMS in based on Chapter 21	✓		
		(ii) determine the extent to which S&E complies with PCT Guidelines	✓		
	(c)	an objective and transparent way	✓		
	(d)	using input incl. information according paragraph 21.17		✓	
	(e)	recording the results	✓		
21.10		Assurance to monitor and adapt to actual workload	✓		
21.11	(a)	Infrastructure in place to ensure that a quantity of staff	✓		
		(i) sufficient to deal with the inflow of work	✓		
		(ii) which maintains tech. qualifications to S&E in all technical fields	✓		
		(iii) which maintains the language facilities to understand languages according to Rule 34	✓		
	(b)	Infrastructure to provide a quantity of skilled administrative staff	✓		
		(i) at a level to support the technically qualified staff	✓		
		(ii) for the documentation records	✓		

21.12	(a)	(i) Ensuring appropriate equipment to carry out S&E	✓		
		(ii) Ensuring documentation accord. to Rule 34	✓		
	(b)	(i) Instructions to help staff understand and act accord. the quality criteria and standards	✓		
		(ii) Instructions to follow work procedures accurately and they are kept up-to-date.	✓		
21.13		(i) L&D program to ensure and maintain necessary skills in S&E	✓		
		(ii) L&D program to ensure awareness of staff to comply with the quality criteria and standards.	✓		
21.14	(a)	System in place for monitoring resources required to deal with demand	✓		
	(b)	System in place for monitoring resources required to comply with the quality standards in S&E	✓		
21.15	(a)	Control mechanisms to ensure timely issue of S&E reports	✓		
	(b)	Control mech. regarding fluctuations in demand and backlog	✓		
21.16	(a)	Internal quality assurance system for self assessment	✓		
		(i) for compliance with S&E Guidelines	✓		
		(ii) for channelling feedback to staff	✓		
	(b)	A system for measurement of data and reporting for continuous improvement	✓		
	(c)	System for verifying the effectiveness of actions taken to correct deficient S&E work	✓		
21.17	(a)	Contact person helping identify best practice between Authorities	✓		
	(b)	Contact person fostering continual improvement	✓		
	(c)	Contact person providing for effective comm. with other Authorities for feedback and evaluation	✓		
21.18	(a)	(i) Appropriate system for handling complaints	✓		
		(ii) Appropriate system for taking preventive/corrective actions	✓		
		(i) Appropriate system for offering feedback to users	✓		
	(b)	(i) A procedure for monitoring user satisfaction & perception	✓		
		(ii) A procedure for ensuring their legitimate needs and expectations are met	✓		
	(c)	Clear and concise guidance on the S&E process for the user	✓		
	(d)	Indication where and how the Authority makes its quality objectives publicly available			✓
21.19		Established comm. with WIPO and desig. + elected offices	✓		

21.20		QMS of Authority clearly described (e.g. Quality Manual)		✓	
21.21	(a)	Documents making up the Quality Manual have been prepared and distributed		✓	
	(b)	Media available to support the Quality Manual	✓		
	(c)	Document control measures are taken	✓		
21.22	(a)	Quality policy of the Authority and commitment to QMS	✓		
	(b)	Scope of QMS		✓	
	(c)	Organizational structure and responsibilities	✓		
	(d)	the documented processes are carried out in the Authority	✓		
	(e)	Resources available to carry out processes	✓		
	(f)	a description of the interaction between the processes and the procedures of the QMS.		✓	
21.23	(a)	Records which documents are kept and where they are kept		✓	
	(b)	Records of results of management review	✓		
	(c)	Records about training, skills and experience of staff	✓		
	(d)	Evidence of conformity of processes	✓		
	(e)	Results of reviews of requirements relating to products	✓		
	(f)	Records of the S&E process carried out on each application	✓		
	(g)	Record of data allowing individual work to be tracked	✓		
	(h)	Record of QMS audits	✓		
	(i)	Records on actions taken re. non-conforming products		✓	
	(j)	Records on actions taken re. corrective actions		✓	
	(k)	Records on actions taken re. preventive actions		✓	
	(l)	Records referring to search process documentation	✓		
21.24	(a)	(i) Recording of the databases consulted during search	✓		
		(ii) Recording of keywords, combination of words and truncations during search	✓		
		(iii) Recording of the languages used during search	✓		
		(iv) Recording of classes and combinations thereof consulted during search	✓		
	(b)	Records about other information relevant to the search	✓		
	(c)	(i) Records about limitation of search and its justification	✓		
		(ii) Records about lack of clarity of the claims	✓		
		(iii) Records about lack of unity	✓		
21.25		Report on its own internal review processes	✓		
21.26-		Additional information on further inputs to its internal reviews	✓		

21.28					
21.29		Initial report called for by paragraph 21.19	✓		

21.06 Indicate with reference to the organizational chart those bodies and mechanisms management uses to ensure:

- (a) the effectiveness of the QMS; and*
- (b) that the process of continual improvement progresses.*

(a)
PDQM is responsible for monitoring and ensuring effectiveness of the QMS

(b)
The DG1/ DG2 Quality Board is responsible for ensuring that continual improvement is achieved by initiating, or providing guidance to, programs and projects related to managing quality.
For further details see 21.08

The DG1 Quality Committee, with representatives of all fourteen Clusters, is responsible for implementation of quality related decisions in Operations.

21.07 Indicate how management of the Authority communicates to its staff the importance of meeting treaty and regulatory requirements including:

- (a) those of this standard; and*
- (b) complying with the Authority's QMS.*

(a)
Activities reports (by top management and PDQM) emphasize the importance of quality.

Results of OQC are presented to all Operational Cluster management teams, and are communicated to examining staff.

(b)
A Quality Management site on the EPO Intranet accessible to all managers reports on QMS activities, objectives and achievements, and in particular the state of development of the EPO's ISO9001 implementation.

Annual President and VP speeches to staff.

21.08 Indicate how and when top management of the Authority or delegated officers:

- (a) conducts management reviews and ensures the availability of appropriate resources;*
- (b) reviews quality objectives; and*
- (c) ensures that the quality objectives are communicated and understood throughout the respective Authority.*

(a) and (c)
A Quality Management Review was held in July 2009 and May 2010 according to the Quality Management Standards set out in ISO 9001:2008. Such reviews are scheduled at least once a year with top management convening to review the performance of its quality management

system against organisational goals and objectives. Issues found during this review are being documented and followed up.

(b)

There is as yet no systematic review of quality objectives themselves.

21.09 Indicate whether top management or delegated officers of the Authority perform an internal review of the QMS in accordance with paragraphs 21.25-21.28:

- (a) at least once per year (cf. paragraph 21.25);*
- (b) in accordance with the minimum scope of such reviews as set out in Section 8, namely:
 - (i) to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.25, 21.27(a));*
 - (ii) to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.25, 21.27(a));**
- (c) in an objective and transparent way (cf. paragraph 21.25);*
- (d) using input including information according to paragraphs 21.27 (b)-(f);*
- (e) recording the results (cf. paragraph 21.28).*

(a)

The last review was held on 17 May 2010.

(b)

(i) This is done in form of this report. The EPO recently achieved compliance with the requirements for the Record of Search.

(ii) Cluster level operational quality control (CL-OQC) is based on a peer to peer check against well-defined criteria, and feedback on the results to the examiner who performed the work.

(c)

see 21.16 below, where the EPO's CL-OQC methodology is described.

(d)

Each of these points form part of the annual review.

(e)

Results of CL-OQC (on Search and Examination work) are presented to the respective management teams by DQMS and each Cluster arranges presentations to their respective S&E staff. The results are also made available to all staff on the EPO's intranet.

The minutes of the management review are published on the Intranet in the management area, providing access to all managers of the EPO.

2. Resources

21.10 Explanatory note: The granting of ISEA status means that the Authority has demonstrated it has the infrastructure and resources to support the search and examination process. Chapter 21 calls for assurance that the Authority can continually support this process while accommodating changes in workload and meeting QMS requirements. The responses to Sections 21.11 to 21.14, below, should provide this assurance.

21.11 Human resources:

- (a) Provide information about the infrastructure in place to ensure that a quantity of staff:
 - (i) sufficient to deal with the inflow of work;*
 - (ii) which maintains the technical qualifications to search and examine in the required technical fields; and*
 - (iii) which maintains the language facilities to understand at least those languages in which the minimum documentation referred to in Rule 34 is written or is translated is maintained and adapted to changes in workload.**
- (b) Describe the infrastructure in place to ensure that a quantity of appropriately trained/skilled administrative staff is maintained and adapted to changes in workload:
 - (i) at a level to support the technically qualified staff and facilitate the search and examination process;*
 - (ii) for the documentation of records.**

(a)

(i) The annually reviewed medium term business plan (MTBP) is the planning tool of the EPO. For planning purposes each DG1 cluster provides an annually updated overview of activities, resources and forecasts of filing numbers. This is drawn up with the help of DG1 directorates Business Analysis and Planning and submitted to upper management. The President/MAC finalizes the MTBP for the office and reports to the AC.

(ii) Examiners are employed according to the technical skills needed in the EPO as given in job descriptions. During their career at the EPO, examiners are regularly enabled to attend conferences or visit companies for technical exchange. For training of staff see point 21.13.

(iii) Staff performing S&E work have to be able to work in all three official languages of the EPO. Courses in all three official languages are regularly offered by DG4.

(b)

(i)(ii) see MTBP under point 21.11 (a) (i) above which fixes staffing levels.

21.12 Material resources:

- (a) Describe the infrastructure in place to ensure that*
 - (i) appropriate equipment and facilities such as IT hardware and software to support the search and examination process are provided and maintained;*
 - (ii) at least the minimum documentation referred to in Rule 34 is available, accessible, properly arranged and maintained for search and examination purposes. State whether it is on paper, in microform or stored on electronic media, and where.*
- (b) Describe how instructions*
 - (i) to help staff understand and adhere to the quality criteria and standards, and*
 - (ii) to follow work procedures accurately and consistently*

are documented, provided to staff, kept up-to-date and adapted when necessary.

(a)

(i) Every examiner is equipped with a working place consisting of a computer with access to the Suite of Examiner applications (SEA) and Internet. SEA is a platform including all relevant software for Classification, Search and Examination. The applications are maintained by Directorate Application Management DG1 in conjunction with DG2 PD Patent Grant Automation (PDPGA).

The eGate project was launched to automate Front End procedures, inter alia to increase the quality of the bibliographic data stored in EPO databases.

Since July 2009 all PCT search copies have been processed through eGate which has reduced processing time.

An automatic check is performed on critical data fields for completeness. If no errors are discovered the respective EPO bibliographic data base is uploaded automatically. Where errors are discovered, corrections are made manually before upload.

(ii) The EPO provides access to internal and external databases for every examiner, thus fulfilling the requirement of Rule 34 PCT. The documentation is stored solely on electronic media. PDPGA in DG2 maintains and ensures the quality of the stored data.

(b).

(i) (ii) The PCT, the EPC, the Guidelines and internal instructions are accessible by all staff via the Single Legal Source (SLS) database and on paper. Updated notes from the DG2 Directorate Practice and Procedure (PPN-notes) are regularly circulated to keep staff up to date about the latest adaptations. PPN notes are superseded by introducing the material covered into the EPO's internal instructions on an (approximately) annual basis. Review takes place as necessary.

21.13 Training resources:

Describe the training and development infrastructure and program which ensures that all staff involved in the search and examination process:

- (i) acquire and maintain the necessary experience and skills; and*
- (ii) are fully aware of the importance of complying with the quality criteria and standards.*

(i) (ii) Examiner training is organized and documented by the Directorate Learning and Development (L&D) in DG4. Initial training for new examiners is a 6 week classroom training. A total of 59 days of classroom training takes place within the first 2 years of employment. Besides classroom training, a tutor assists the newcomer for the first two years in his daily work. Experienced examiners receive further courses on specific procedural issues (e.g. opposition) of the patent granting procedure. However it is not systematically provided to all examiners.

Formalities officer (FO) training is also organized by L&D. Initial training is dependent on the procedures they are employed for and is 2-4 weeks classroom training. Coaches support the FO's work whenever needed. Additional procedures are trained either on the job or in a specified classroom training followed by coach assistance at the discretion of the line manager.

21.14 Oversight over resources:

Describe the system in place for continuously monitoring and identifying the resources required:

- (a) to deal with demand; and*
- (b) comply with the quality standards for search and examination*

(a) (b)

The Human Resource department and L&D work in the same DG and exchange information. DG1 PD Business Services performs calculation of capacity and the MTBP fixes the planning for resources.

3. Management of administrative workload

21.15 Indicate how the following practices and procedures for handling search and examination requests and performing related functions such as data-entry and classification are implemented:

- (a) Effective control mechanisms regarding timely issue of search and examination reports to a quality standard as set by the respective Authority; and*
- (b) Appropriate control mechanisms regarding fluctuations in demand and backlog management.*

(a)

Each manager has access to Management of Unified Search and Examination system (MUSE). A "Megalist" application is used to monitor priorities, timeliness, backlog and requests for S&E. The data provided by the Megalist is available in additional sources e.g. Balanced Score Card (BSC), Dashboard.

In DG1, Cluster Business Administrators (CBA) provide a monthly report to Directors and Principal Directors giving operational statistics.

The "Classification Portal" is the tool used by Directors to monitor workload and timeliness of classification work performed by examiners.

(b)

see (a) above. The MUSE system highlights these issues and allows backlog management. Backlog reports are prepared by DG1 PD Business Services on a monthly basis.

4. Quality assurance

21.16 The following are required quality assurance measures for timely issue of search and examination reports of a quality standard in accordance with the Guidelines. Indicate how the following are implemented:

- (a) An internal quality assurance system for self assessment, involving verification, validation and monitoring of searches and examination work:
 - (i) for compliance with these Search and Examination Guidelines;*
 - (ii) for channelling feedback to staff.**
- (b) A system of measurement and collection of data and reporting. Show how the Authority uses the system to ensure the continuous improvement of the established processes.*
- (c) A system for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes, and to prevent issues from recurring.*

(a)

(i) CL-OQC (Cluster-level Operational Quality Control) now includes checking of work across the three sites of DG1 Operations (Munich, The Hague, Berlin) to identify site-related differences in practice and to harmonize working procedures. Corrective action is taken - where necessary - to ensure that work is produced to the same standards at each site. Around 1% of total production is checked across sites and 5% on-site. A dedicated CL-OQC sampling, checking and reporting procedure provides each JC with six-monthly reports on the nature and extent of deficiencies of S&E work performed under the PCT. A total of 13137 applications were checked under CL-OQC during 2009, 1844 of these were checked across sites and 4283 of these filed under the PCT.

A harmonised approach ensuring corrective action for S&E work on the basis of CL-OQC results across all JCs was developed by the DG1 / DG2 Quality board assisted by L&D. Field- specific training on clarity objections and added subject-matter (See 21.17 below) was continued in 2009.

Presentations of CL-OQC results for 2009 were made to all operational management teams. These presentations were cascaded to all examination staff in 1st half of 2010.

Extension of the PA-OQC methodology (Patent Administration Operational Quality Control) for patent search and granting administration and formalities in the DG2 Principal Directorate Patent Administration (PD Pat. Admin.) by checking the process of EP and PCT search non-unity as well as the receiving section for WIPO.

A pilot for classification operational quality control (Class-OQC) based on the CL-OQC methodology was evaluated this year. The pilot checks classification of all incoming documents and dossiers at the time of search by an experienced classifier who traditionally administers classification practice in a given field. The aim is to document classification practice and check the work of other classifiers in the team, perform correction and initiate corrective action when necessary. After evaluating the pilot, it will be extended to more fields in 2010-2011.

In-depth post-production checks on a statistically significant sample of examination and search products (750 and 350 respectively) were carried out by Directorate Quality Audit (DQA) of PD Internal Audit in 2009. The results indicate the extent of compliance of the search and examination products produced by the office as a whole.

(ii) Presentations of CL-OQC results are given annually to DG1 Cluster management teams and subsequently to staff. The EPO is in the process of making CL-OQC results available to all staff.

Results of the PA-OQC methodology are distributed via review sessions as each batch is checked.

DQA gives annual presentations of quality audit results to DG1 management teams.

(b)

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(c)

see DQA, PA-OQC and CL-OQC under point 21.16 (a) (i) above.

5. Communication

21.17 Inter-Authority communication:

Provide the name, job title and contact details of the Authorities designated quality contact person who will take responsibility for:

- (a) *helping identify and disseminate best practice among Authorities;*
- (b) *fostering continual improvement; and*
- (c) *providing for effective communication with other Authorities to allow for prompt feedback from them so that potential systemic issues can be evaluated and addressed.*

(a - c)

Director DQMS and his directorate within DG2 Principal Directorate QM. Current director is Hubert Plugge. He can be contacted via the email address dqms@epo.org

21.18 Communication and guidance to users:

Describe the system in place for monitoring and using customer feedback including at least the following elements:

- (a) *An appropriate system for*
 - (i) *handling complaints and making corrections;*
 - (ii) *taking corrective and/or preventative action where appropriate; and*
 - (iii) *offering feedback to users.*
- (b) *A procedure for:*
 - (i) *monitoring user satisfaction and perception; and*
 - (ii) *for ensuring their legitimate needs and expectations are met.*
- (c) *Clear, concise and comprehensive guidance and information to users (particularly unrepresented applicants) on the search and examination process, giving details of where it is to be found e.g. link to Authority's web site, guidance literature.*
- (d) *An indication of where and how the Authority makes its quality objectives publicly available for the users.*

(a)

(i) Complaints are handled by DQMS together with the respective line manager.

(ii) The L&D and DPP directorates in DG4 and DG2 respectively are responsible for developing training and instructions in response to requests from the operational line or strategic programs. Quality issues requiring corrective or preventive action are registered in a quality improvement database (EQUID).

(iii) "Partnership for Quality" meetings arranged by PDQM support the exchange between the EPO and professional bodies, in Europe and the US.

(b)

(i)(ii) User Satisfaction Surveys were carried out between 2007 and 2009 on the search and examination work of all fourteen Joint Clusters.

Results were presented to the management teams of these Joint Clusters in 2009.

(c)

Given in Guidelines for filing applications and the Applicants Handbook, available via the office web site under "Patents" → "Grant Procedure".

(d)

The EPO does not publish externally quantitative quality objectives.

21.19 Communication with WIPO and designated and elected Offices:

Describe how the Authority provides for effective communication with WIPO and designated and elected offices. In particular describe how the Authority ensures that WIPO feedback is promptly evaluated and addressed

Several departments of the EPO e.g. PDQM, DG2, PDIM are designated to regularly attend WIPO meetings. Feedback from WIPO is addressed by these departments. Quality matters are addressed directly to DQM (see 21.17, above).

6. Documentation

21.20 Explanatory note: *The QMS of the Authority needs to be clearly described and implemented so that all processes in the Authority and the resulting products and services can be monitored, controlled, and checked for conformity. This is done in the documents that make up the Quality Manual of the Authority (see paragraph 21.21).*

(Note: This point is informative. No response is required by the template to paragraph 21.20)

21.21 *The documents that make up the Quality Manual serve to document the procedures and processes affecting the quality of work, such as classification, search, examination and related administrative work. In particular, the Quality Manual indicates where to find instructions on the procedures to be followed.*

For the purposes of this report indicate:

- (a) the documents making up a Quality Manual that have been prepared and distributed;*
- (b) the media on which it is supported (e.g. Internal Publication, Internet, Intranet); and*
- (c) document control measures taken e.g. version numbering, access to latest version.*

(a)

The documents are currently under development and form part of the ISO-Implementation Project (IIP). Release is planned for 2011.

(b)

The Quality Manual will be available on the EPO Intranet to all staff upon completion of IIP.

(c)

Document control will be part of the Quality Manual and is a requirement under ISO 9001.

21.22 Indicate whether the documents making up the Quality Manual include the following:

- (a) the quality policy of the Authority including a clear statement of commitment to the QMS from top management;
- (b) the scope of the QMS, including details of and justification for any exclusions;
- (c) the organizational structure of the Authority and the responsibilities of each of its departments;
- (d) the documented processes carried out in the Authority such as receipt of incoming applications, classification, distribution, search, examination, publication and support processes, and procedures established for the QMS, or references to them;
- (e) the resources available for carrying out the processes and implementing the procedures; and
- (f) a description of the interaction between the processes and the procedures of the QMS.

(a - f)

These documents will be included in the full QMS . They are under development and form part of the current ISO9001 project.

21.23 Indicate which types of records the Authority maintains, such as:

- (a) a definition of which documents are kept and where they are kept;
- (b) results of management review;
- (c) training, skills and experience of personnel;
- (d) evidence of conformity of processes, resulting products and services in terms of quality standards;
- (e) results of reviews of requirements relating to products;
- (f) the search and examination processes carried out on each application;
- (g) data allowing individual work to be tracked and traced;
- (h) records of QMS audits;
- (i) actions taken re. non-conforming products, e.g. examples of corrections;
- (j) actions taken re. corrective action;
- (k) actions taken re. preventative action; and
- (l) search process documentation as set out in Section 7.

(a)(b)

The protocol for maintaining records is placed on the management area on the Intranet, available to all EPO managers.

(c)

Records of all qualifications and training received are kept in FIPS (Finance and Personnel System) by the Human Resources department (DG4).

(d)
Results of OQC are available to all staff in a DG specific Balanced Scorecard (BSC).

(e)
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(f)
All communications and the search documentation for each application are centrally stored.

(g)
see (f) above

(h)
Records of QMS audits are kept in a central Audit database administered by the respective DG.

(i)
The EPO has two mechanisms to detect non-conforming products in S&E during the PCT phase. Checks by the Director and CL-OQC. Quality issues are discussed with the 1st examiner, corrections are at the discretion of the Examiner.

(j)
Corrective actions in form of training are recorded under (c). issues are recorded in the European Quality Improvement Database (EQUID) to be followed-up by the responsible manager.

(k)
Preventive actions in form of training are recorded under (c).

(l)
-

7. Search process documentation

21.24 *For internal purposes the Authority should document its search process.*

The Authority should indicate

- (a) *which of the following are included in this record:*
 - (i) *the databases consulted (patent and non patent literature);*
 - (ii) *the keywords, combinations of words and truncations used;*
 - (iii) *the language(s) in which the search was carried out;*
 - (iv) *the classes and class combinations searched, at least according to the IPC or equivalent;*
 - (v) *a listing of all search statements used in the databases consulted.*
- (b) *which other information relevant to the search itself is included in this record e.g. a statement of the subject of search; details of special relevance to internet searching; a record of documents viewed; on-line thesaurus, synonym or concept databases, etc.*

(Explanatory note: The IA is requested to list other information it may collect to monitor and improve the search process)
- (c) *which special cases are documented and whether records are kept denoting any:*
 - (i) *limitation of search and its justification*
 - (ii) *lack of clarity of the claims; and*
 - (iii) *lack of unity.*

(a)-(c)

The office implemented a mandatory record of the search process, traditionally called the "Compte Rendu de Recherche" (CRdR), as from 1. July 2010. Internal instructions (PPN 4/10) for recording searches in the CRdR are established and have been communicated to the examiners. They are specific for each of the fourteen technical areas. Every CRdR must indicate briefly "what", "where" and "how" was searched (Subject, Scope and Strategy of Search).

In view of (v) the examiner must indicated how their searches were performed (strategy)

8. Internal review

21.25 *Explanatory note: The Authority should report on its own internal review arrangements. These reviews determine the extent to which it has established a QMS based on the model of Chapter 21 and the extent to which it is complying with the QMS requirements and the Search and Examination Guidelines. The reviews should be objective and transparent to demonstrate whether or not those requirements and guidelines are being applied consistently and effectively and should be undertaken at least once a year. With reference to point 21.08 of this template, the Authority may provide additional information on its internal review arrangements under this section if it so wishes.*

21.26-21.28 *These arrangements are reported according to this template in Section 1, above, at points 21.04 - 21.09. The Authority may provide additional information on further inputs to its internal reviews under this section, if it so wishes*

21.25

The first review according to Chapter 21.10 carried out in 2007 identified actions necessary to ensure that (a), (b) and (c) are consistently met. The status of these was reported to top management in June 2008 (see response to §21.07(b) above).

An Internal Review was held in July 2009 and repeated in May 2010. Top management convened to review the performance of its quality management system against organisational goals and objectives. Issues found during this reviews needed follow up. One of these issues concerns the Office's Quality Policy which will be updated to reflect the Office's new Mission. Another of these issues concerns the Office's BSC in which the Key Performance Indicator (KPI) currently fails to reflect the results of User Satisfaction Surveys.

21.26-21.28

An extensive process-audit of the entire CL-OQC procedure was performed in 2008. Recommendations for improving the process and in particular its documentation were addressed and implemented in 2009.

The DG1/DG2 Quality Board met four times in 2009 and two times in 2010. It decided to align the checklists on clarity for CL-OQC and Quality Audit. A critical review of results generated by PA-OQC, the User Satisfaction Survey (USS) and the complaints received by the office took place and fields of improvement were identified.

CL-OQC results highlighted the need for corrective actions in some areas of examination work, notably clarity of the claimed subject matter. The DG1/DG2 Quality Board launched these in 2008, implemented them in 2009 and will monitor progress in 2010.

9. Arrangements for Authorities to Report to the MIA

21.29 There are two stages in the reporting arrangements. The document up to this point relates to the initial report called for by paragraph 21.29. It will be supplemented annually by further reports in accordance with paragraph 21.30.

[End of document]