

ORIGINAL: ENGLISH DATE: NOVEMBER 16, 2014

### PATENT COOPERATION TREATY (PCT)

# Common Quality Framework for International Search and Preliminary Examination

#### SUPPLEMENTAL REPORT ON QUALITY MANAGEMENT SYSTEMS

prepared by EUROPEAN PATENT OFFICE

This supplemental report relates to the quality management system established by this Office as set forth in our report under PCT/GL/ISPE section 21.29 on 12 October 2010.

As a result of our most recent internal review under the International Search and Preliminary Examination Guidelines paragraphs 21.25-21.28, this Authority has made modifications to its QMS as discussed below.

The modifications are given with reference to the sections of the revised template for responses to PCT/GL/ISPE Chapter 21.29 to which the changes relate.

The Authority should describe any changes made to its QMS making reference to the specific sections of the previous main report, and/or making reference to any supplemental report(s) under paragraph 21.30 compiled in accordance with this template.

If no changes have been made to its QMS since the last report, the Authority should indicate such.

#### **INTRODUCTION (PARAGRAPHS 21.01 TO 21.03)**

The quality of the products and services delivered by the EPO is recognised across the patent world and EPO management is committed to maintain and even enhance the Office's leading position. This Office aims to achieve this by sustaining a strong and effective commitment to quality at all levels. In 2014- the Quality Management System for the patent granting process of the Office has been certified ISO 9001:2008.

#### 1. LEADERSHIP AND POLICY (PARAGRAPHS 21.04 TO 21.09)

- 21.04 Confirm that the following are clearly documented, and that this documentation is available internally:
  - (a) The quality policy established by top management.

The EPO is dedicated to meet its stakeholders' needs and expectations and to remain global quality leader of patent products and services. The performance and reliability of the EPO are based on the professional competence and personal responsibility of its management and staff.

The management and staff commit themselves to the following principles:

• Legal certainty - The users of the European patent system expect that patents granted by the EPO have the highest presumption of legal validity. The EPO therefore grants patents and provides decisions fully consistent with the applicable legal framework, in particular the requirements of the EPC and other international treaties in both an efficient and timely manner.

• Service - The EPO provides reliable, efficient and effective services for the benefit and satisfaction of all users of the European patent system and the European society.

• Continual improvement - The EPO commits itself to continually improving its training, tools, procedures and processes for enhancing the thoroughness, consistency, and timeliness of its products and services and the skills and competences of its staff.

• Involvement - The EPO has a culture that encourages and empowers management and staff to participate in quality improvement activities.

• Informed decision making - Decisions taken at the EPO are based on facts enabling to review, challenge and adapt planned actions as well as to improve the products and services delivered by the EPO.

• Openness - The EPO engages with its users to enhance the quality and effectiveness of its processes and services.

• Commitment - The top management of the EPO is committed to this Quality Policy through active participation in quality improvement activities and leadership by example.

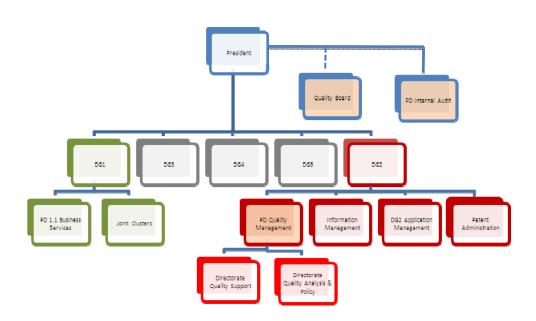
In pursuing the above-mentioned principles the EPO builds on the culture of quality and excellence that has established its reputation.

- (b) The roles and names of those bodies and individuals responsible for the QMS, as delegated by top management.
- President: The President has the overall responsibility for the QMS. He establishes the Quality Policy and quality objectives to support the QMS.
- The Management Representative for Quality: The Management Representative for Quality coordinates the implementation, maintenance and improvement of the QMS at all levels of the organization. This role is assigned to the Vice-President of Directorate General 2.
- Quality Board: The Quality Board ensures the integration of the Quality Management System into the Office's management system. It has the function to evaluate the effectiveness the Quality Management System and support it by recommending and monitoring the implementation of improvement measures.
- Principal Directorate Quality Management: This Principal Directorate has a centralised oversight of all quality aspects. It is dedicated to the design, implementation and maintenance of a Quality Management System for the patent-grant process. The activities and responsibilities of this Principal Directorate aim to suit the needs of internal and external stakeholders under the framework of the Quality Management System for the

patent-grant process. It also works closely with Operations by supporting, informing and guiding in quality principles.

As of July 2013, Principal Directorate Quality Management includes two Directorates: Directorate Quality Analysis & Policy (responsible for facilitating the policy making process by providing information, data, metrics analysis and recommendations to management) and Directorate Quality Support (responsible for managing the Quality Management System by the development and maintenance of quality services).

(c) An organizational chart showing all those bodies and individuals responsible for the QMS.



21.05 Indicate (e.g. by means of a table as shown below) 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>~</b>	
	(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	<b>~</b>	
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	<ul> <li>✓</li> </ul>	
	(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)	<ul> <li>(i) Instructions to help staff understand and act accord.</li> <li>the quality criteria and standards</li> </ul>	~	
		(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	~	

	1			, <u>, , , , , , , , , , , , , , , , , , </u>	
	(b)	System in place for monitoring resources required to comply with the quality standards in S&E	$\checkmark$		
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	$\checkmark$		
		(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	$\checkmark$		
	(c)	Contact person providing for effective comm. with other Authorities for feedback and evaluation	$\checkmark$		
21.18	(a)	(i) Appropriate system for handling complaints	$\checkmark$		
		(ii) Appropriate system for taking preventive/corrective actions	✓		
		(i) Appropriate system for offering feedback to users	$\checkmark$		
	(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	$\checkmark$		
21.20		QMS of Authority clearly described (e.g. Quality Manual)	$\checkmark$		
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	$\checkmark$		
21.22	(a)	Quality policy of the Authority and commitment to QMS	$\checkmark$		
	(b)	Scope of QMS	√		
	(c)	Organizational structure and responsibilities	$\checkmark$		

	(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	$\checkmark$	
	(c)	Records about training, skills and experience of staff	$\checkmark$	
	(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	$\checkmark$	
	(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	~	
	(I)	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	$\checkmark$	
		(iv) Recording of classes and combinations thereof consulted during search	~	
	(b)	Records about other information relevant to the search	$\checkmark$	
	(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-	Ī	Additional information on further inputs to its internal	✓	

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

(a) the effectiveness of the QMS; and

See bodies listed in §21.04(b). A Quality Management Review is carried out every year in order to review the effectiveness of the QMS.

(b) that the process of continual improvement progresses.

- The results of quality controls serve together with other feedbacks as a basis for identifying corrective and preventive and improvement actions (e.g. providing specific training for staff, implementing suitable changes in practice and procedures, etc.). The implementation and the effectiveness of these actions are monitored by operational departments as well as by the Quality Board. A Quality Management Review is carried out every year in order to assess the efficiency and effectiveness of the Quality Management System. The continual improvement of the QMS is regularly followed up at the Quality Management Review.
- 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
  - Activities reports (by top management and Principal Directorate Quality Management) emphasize the importance of quality, as degree to which products characteristics fulfils the treaty and regulatory requirements. Furthermore, quality data in the form of "Quality Reports" are presented to all Operational management teams, and are communicated to staff.
    - (b) complying with the Authority's QMS.
  - Internal communiqués by top management regarding the Quality Management System implementation, the yearly quality objectives and results achieved in the previous year. Further communication means are used to address quality matters to all levels of the organization (e.g. intranet quality site, posters, flyers, workshops, training/awareness sessions)
- 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) to (c) The management of the EPO reviews the QMS at regular intervals on its effectiveness, suitability and adequacy and in order to follow up continual improvement and user satisfaction. This is carried out through review meetings. This review also applies to the quality objectives which are communicated to staff.
- 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);
  - The evaluation of the Quality Management System is presently carried out on a yearly basis.
    - (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));
  - The QMS is reviewed during the management review.

(ii) to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.25, 21.27(a));

• The achievement of quality objectives related to search and examination is reviewed during the management review.

(c) in an objective and transparent way (cf. paragraph 21.25);

• The QMS is reviewed considering quality objectives and key performance indicators related to processes and products.

- (d) using input including information according to paragraphs 21.27 (b)-(f);
- Each of these points forms part of the annual Management Review.
  - (e) recording the results (cf. paragraph 21.28).
- Outputs from the management review are recorded.

#### 2. RESOURCES (PARAGRAPHS 21.10 TO 21.14)

- 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;

• Human resources planning is done according to a medium term business plan (MTBP) which is annually reviewed depending on operational needs. The President, after consulting the Management Advisory Committee, approves the MTBP for the office and reports to the Administrative Council.

(ii) which maintains the technical qualifications to search and examine in the required technical fields; and

• Examiners and Formalities Officers are recruited according to the skills as required by the particular job descriptions. They also receive training during their career at the EPO (see point 21.13).

- (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.
- Examiners at the EPO must be able to work in all three official languages of the Office. To that purpose the Office offers suitable courses on a regular basis.
  - (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.
- (i)(ii) staffing levels are fixed by the MTBP (see point 21.11 (a) (i) above).
- 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;
  - Every examiner and Formalities Officer is equipped with a working place consisting of a computer with access to a platform including all relevant software for Classification, Search and Examination and Internet.. The applications are maintained by Directorate Application Management DG1, Directorate Application Management DG2 and Principal Directorate Service Creation.
    - (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.
  - Every examiner has access to internal and external databases in accordance to the requirement of Rule 34 PCT. The documentation is stored solely on electronic media. PDPGA maintains and ensures the quality of the stored data.
    - (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.
  - (i) and (ii) The relevant legal texts and instructions (e.g. PCT, EPC, Guidelines and internal instructions) are accessible to all staff via the external EPO website and via intranet. Staff is kept up to date about the latest adaptations by means of dedicated Practice and Procedure Notes.
- 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) Training for examiners and formalities officers is organized and documented by Directorate Recruitment & Talent Management in DG4. The initial training for new examiners is a 6 week classroom training. Within the first 2 years of employment examiners receive a total of 59 days of classroom and are assisted by a tutor in their daily work. Experienced examiners receive further courses on specific procedural issues (e.g. opposition) of the patent granting procedure. Formalities officers receive an initial 2-4 weeks classroom training according to the procedures they are employed for and are supported by a coach whenever needed. Afterwards they receive training on additional procedures 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 Directorate Recruitment & Talent Management is part of the Principal Directorate Human Resources. Directorate Business Analysis and Planning which is part of Principal Directorate Business Services is in charge for providing estimates of human resources required in DG1 on an annual basis (see 21.11 above).

#### 3. MANAGEMENT OF ADMINISTRATIVE WORKLOAD (PARAGRAPH 21.15)

- 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
  - DG1 Managers have access to a number of software applications which allow them the monitoring and managing priorities, timeliness, backlog and requests for search and examination. Principal Directorate Business Services provide monthly reports with operational statistics to Directors and Principal Directors in DG1.
    - (b) Appropriate control mechanisms regarding fluctuations in demand and backlog management.
  - Backlog reports are prepared by DG1 PD Business Services on a monthly basis (see also (a) above).

#### 4. QUALITY ASSURANCE (PARAGRAPH 21.16)

- 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;
  - Since 2012 the Quality Board proposes quality objectives according to the strategy for quality, which objectives are endorsed by top management.
  - Quality-related results are presented to operational management teams using integrated quality reports. These reports focus on key quality issues and present the most relevant quality aspects which can be derived from different quality-related data sources, e.g. user satisfaction surveys, operational quality control, quality indicators, complaints.

- Identification of the key quality issues allow development of corrective, preventive and/or improvement actions, which efficiency is then monitored.
- As of 2014 Operational Quality Control in DG1 is done according to a procedure called "conformity assurance in search and examination". According to this procedure, a record is kept of any nonconformity detected and also of the re-verification step and correction which is taken before releasing the product.
- The methodology applied for carrying out Patent Administration Operational Quality Control (PA-OQC) has been improved in 2014 to better suit business needs. The improved methodology is now fully integrated into the Office's Quality Management System and the results from the first two sets of findings from monitored products are currently used to generate corrective actions to be integrated into the Quality Action Plan 2015.
- Results from Classification operational quality control (Class-OQC) based on the sample of documents checked in 2013-2014 have been reported to Management in the framework of integrated quality reports. Bilateral quality assurance for CPC is ongoing, based on both sampled checks by classification Quality Nominees in the EPO and the USPTO and statistical comparison of patent families independently classified with CPC symbols by both offices.
  - (ii) for channeling feedback to staff.
- see point 21.16 (a) (i) above.

#### 5. COMMUNICATION (PARAGRAPHS 21.17 TO 21.19)

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.
- The Senior Management Representative for Quality (Vice-President DG2) who can be contacted via the e-mail address <u>VP2@epo.org</u>.
- The Operational Management Representative for Quality (Principal Director of Principal Directorate Quality Management) who can be contacted via quality@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;
- Directorate Quality Support is responsible for the administration and management of external complaints submitted at the EPO. Depending on the nature of the complaint, other

departments are involved in the complaint handling procedure (e.g. for providing feedback and (if required) for taking suitable corrective and/or preventive actions). As of 01.01.2014, the EPO web site has a web form for submitting complaints online.

- (ii) taking corrective and/or preventative action where appropriate; and
- An analysis of the customers feedback that is received in the form of complaints and within the framework of user satisfaction surveys is part of the Annual Quality Report which is the document used as the basis for defining the annual quality objectives and quality action plans for DG1 and Patent Administration. Quality issues requiring corrective or preventive action are registered in a quality improvement database.
- The EPO has established and maintains a documented Corrective Action Procedure for eliminating the causes of nonconformity and prevent recurrence as well as a documented Preventive Action Procedure for eliminating the causes of potential nonconformities and prevent occurrence. Corrective and preventive actions taken are appropriate to the impact of the problems encountered. The actions taken and follow-up activities resulting from corrective and preventive actions are documented and recorded in a dedicated specific database.
  - (iii) offering feedback to users.
- "Partnership for Quality" meetings support the exchange between the EPO and professional bodies within the IP5 countries.
  - (b) A procedure for:
    - (i) monitoring user satisfaction and perception; and
    - (ii) for ensuring their legitimate needs and expectations are met.
- (i) and (ii) A user satisfaction survey covering search and examination products and services delivered by all DG1 Joint Clusters is completed every three years. User satisfaction with specific products and services provided by Patent Administration is monitored by means of an online survey which is carried out every two years. Feedback provided by users in reply to the questionnaires of the surveys is analysed to detect quality issues and any other cause for dissatisfaction which need to be addressed by the Process Owners when developing the annual Quality Action Plan.
  - (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.
- A Guide for applicants is available on the office's web site under <u>http://www.epo.org/applying.html</u>.
  - (d) An indication of where and how the Authority makes its quality objectives publicly available for the users.

• In 2015 the EPO will start publishing some information related to the quality of its products and services.

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 are designated to regularly attend WIPO meetings. Feedback from WIPO is addressed by the relevant departments; in particular feedback related to quality matters is addressed by Principal Directorate Quality Management (see 21.17, above).

#### 6. DOCUMENTATION (PARAGRAPHS 21.20 TO 21.23)

- 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;
- The Quality Manual and the Manual of procedures is available to all staff via the EPO's intranet site dedicated to quality.
  - (b) the media on which it is supported (e.g. Internal Publication, Internet, Intranet); and
- See (a) above.
   (c) document control measures taken e.g. version numbering, access to latest version.
- The implemented document control complies with the requirement of the standard under ISO 9001:2008.
- 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) to (f) These documents are all included in the Quality Manual, either as such, or incorporated by reference to the Manual of Procedures.
- 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;
- (a) and (b) Relevant documentation and locations are defined in the QMS documentation. Management review documentation, including its outcome, is kept in a database administered by the Quality Board.
  - (c) training, skills and experience of personnel;
- Records of staff competencies, development and training received are kept in a database administered by Principal Directorate Human Resources. Staff have access to these records via FIPS (Finance and Personnel System) and via MyTalent LMS (Learning Management System)
  - (d) evidence of conformity of processes, resulting products and services in terms of quality standards;
- Certification of the QMS according to ISO 9001:2008 standard.
  - (e) results of reviews of requirements relating to products;
- yes, where applicable. The results of reviews are stored in internal databases.
  - (f) the search and examination processes carried out on each application;
- The whole documentation on all search and examination processes carried out on an application makes up the content of the electronic file and is centrally stored.
  - (g) data allowing individual work to be tracked and traced;
- see (f) above
  - (h) records of QMS audits;
- Records of QMS audits are kept in a central Audit database administered by Principal Directorate Internal Audit.
  - (i) actions taken re. non-conforming products, e.g. examples of corrections;
- The EPO has two mechanisms to detect non-conforming products in search and examination during the PCT phase; i.e. checks by the Director and checks by a different examiner. Detected non-conformities and the respective corrections of the non-conforming products are registered in a dedicated database and discussed with the entrusted examiner.
  - (j) actions taken re. corrective action;
- Records of detected recurrent non-conformities and the corrective actions taken to address their root cause are kept in a dedicated database.
  - (k) actions taken re. preventative action; and

• Process performance is monitored using Key Performance Indicators (KPIs) which are specifically defined by the Process Owner. The EPO has a system in place that generates a warning when a KPI falls below a threshold value. This allows the Process Owner to take suitable preventive actions for ensuring that the objectives set for the process are met. Records of preventive actions are kept in a dedicated database.

- (I) search process documentation.
  - See section 7 below.

#### 7. SEARCH PROCESS DOCUMENTATION (PARAGRAPH 21.24)

- 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) to (c) Examiners must keep a record of the search process since 1. July 2010. The search records must indicate briefly "what", "where" and "how" was searched (Subject, Scope and Strategy of Search). Examiners must also indicate how their searches were performed (strategy).

#### 8. INTERNAL REVIEW (PARAGRAPHS 21.25 TO 21.28)

- 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.
  - 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. This finding was communicated to to top management in June 2008 and since then annual internal reviews have been carried out with the aim to review the performance of its quality management system against organisational goals and objectives. These efforts have ultimately led to ISO certification for the Patent Grant Process in 2014.

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

[End of document]