

Patent Cooperation Treaty (PCT)

Common Quality Framework for International Search and Preliminary Examination

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 European Patent Office acts as International Searching Authority and International Preliminary Examination Authority since 1978.](#)

The quality of the products and services delivered by the EPO is recognized 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 (QMS) of the Office has been certified ISO 9001:2008 for the patent granting process, which includes the PCT Search and Examination.

In 2015 the QMS has extended the scope of certification to Patent Information and post-grant activities. As a result the new scope of the ISO 9001:2008 certified QMS is the Patent Process.

[In 2016 the Office is preparing the extension of the scope of certification to the Unitary Patent Protection process. Moreover the Office is working on the transition of the QMS to the new version 2015 of the ISO 9001 standard. The certification according to the new standard is expected for the 2017](#)

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 organizational chart showing all those bodies and individuals responsible for the QMS.*

(a) The Quality Policy of the EPO is available internally (e.g. intranet, posters, gadgets) and published on EPO website at <http://www.epo.org/about-us/office/quality/policy.html>.

The Quality Policy is as follows:

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) President: The President has the overall responsibility for the QMS. He establishes the Quality Policy and quality objectives to support the QMS.

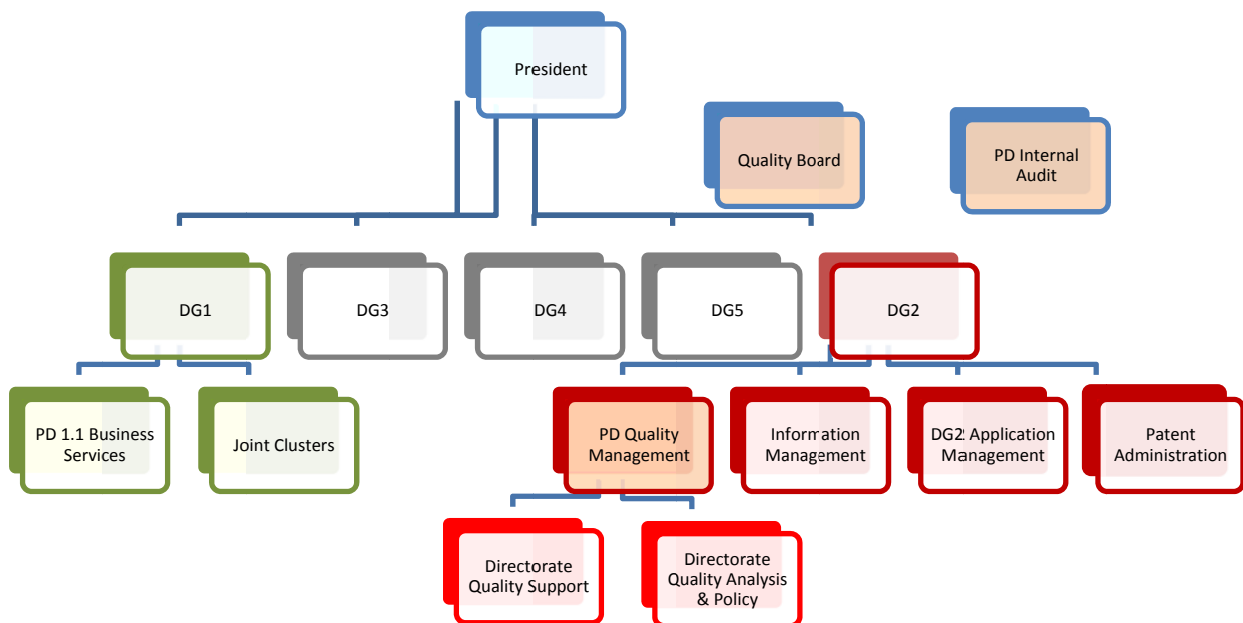
The Management Representative for Quality: The Management Representative for Quality coordinates the implementation, maintenance and improvement of the QMS at all levels of the organization. This role is assigned to the Vice-President of Directorate General 2.

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 centralized 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)



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

Chapter 21 requirement				Extent of compliance		
				full	part	no
21.04		(a)	Quality policy available	✓		
		(b)	Identified roles and names for QMS responsibility	✓		
		(c)	Organizational 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)	determine the extent to which the QMS is based on Chapter 21	✓		
			determine the extent to which S&E complies with PCT Guidelines	✓		
		(c)	an objective and transparent way	✓		
		(d)	using input incl. information according paragraph 21.24	✓		
		(e)	recording the results	✓		
21.10			Assurance to monitor and adapt to actual workload	✓		
	(i)		Infrastructure in place to ensure that a quantity of staff	✓		
		(a)	sufficient to deal with the inflow of work	✓		
		(b)	which maintains tech. qualifications to S&E in all technical fields	✓		
		(c)	which maintains the language facilities to understand languages according to Rule 34	✓		
	(ii)		Infrastructure to provide a quantity of skilled administrative staff	✓		
		(a)	at a level to support the technically qualified staff	✓		
		(b)	for the documentation records	✓		
	(iii)		Ensuring appropriate equipment to carry out S&E	✓		
	(iv)		Ensuring documentation accord. to Rule 34	✓		
	(v)	(a)	Instructions to help staff understand and act accord. the quality criteria and standards	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
		(b) Instructions to follow work procedures accurately and they are kept up-to-date.	✓		
	(vi)	(a) Training and development program to ensure and maintain necessary skills in search and examination	✓		
		(b) Training and development program to ensure awareness of staff to comply with the quality criteria and standards.	✓		
	(vii)	(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	✓		
21.11	(i)	Control mechanisms to ensure timely issue of S&E reports	✓		
	(ii)	Control mech. regarding fluctuations in demand and backlog	✓		
21.12	(i)	Internal quality assurance system for self-assessment	✓		
		(a) for compliance with S&E Guidelines	✓		
		(b) for channeling feedback to staff	✓		
	(ii)	System for measurement of data and reporting for continuous improvement	✓		
	(iii)	System for verifying the effectiveness of actions taken to correct deficient S&E work	✓		
21.14		(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	✓		
21.15	(i)	(a) Appropriate system for handling complaints	✓		
		(b) Appropriate system for taking preventive/corrective actions	✓		
		(c) Appropriate system for offering feedback to users	✓		
	(ii)	(a) A procedure for monitoring user satisfaction & perception	✓		
		(b) A procedure for ensuring their legitimate needs and expectations are met	✓		
	(iii)	Clear and concise guidance on the S&E process for the user	✓		
	(iv)	Indication where and how the Authority makes its quality objectives publicly available	✓		
21.16		Established communication with WIPO and designated and elected Offices	✓		
21.17		QMS of Authority clearly described (e.g. Quality Manual)	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
21.18	(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	✓		
21.19	(i)	Quality policy of the Authority and commitment to QMS	✓		
	(ii)	Scope of QMS	✓		
	(iii)	Organizational structure and responsibilities	✓		
	(iv)	the documented processes are carried out in the Authority	✓		
	(v)	Resources available to carry out processes and implementing the procedures	✓		
	(vi)	a description of the interaction between the processes and the procedures of the QMS.	✓		
21.20	(i)	Records which documents are kept and where they are kept	✓		
	(ii)	Records of results of management review	✓		
	(iii)	Records about training, skills and experience of staff	✓		
	(iv)	Evidence of conformity of processes	✓		
	(v)	Results of reviews of requirements relating to products	✓		
	(vi)	Records of the S&E process carried out on each application	✓		
	(vii)	Record of data allowing individual work to be tracked	✓		
	(viii)	Record of QMS audits	✓		
	(ix)	Records on actions taken re. non-conforming products	✓		
	(x)	Records on actions taken re. corrective actions	✓		
	(xi)	Records on actions taken re. preventive actions	✓		
	(xii)	Records referring to search process documentation	✓		
21.21	(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	✓		
	(v)	Recording of a listing of all search statements used in databases consulted	✓		
	(vi)	Records about other information relevant to the search	✓		
	(vii)	Records about limitation of search and its justification	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
	(viii)		Records about lack of clarity of the claims	✓		
	(ix)		Records about lack of unity	✓		
21.22			Report on its own internal review processes	✓		
21.23-21.25			Additional information on further inputs to its internal reviews	✓		
21.26			Initial report called for by paragraph 21.26	✓		

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.*

Monitoring and measurements of the processes, monitoring and measurements of products' and services' conformity, the monitoring of users' satisfaction, the results from internal audits and external audits (e.g. certification or surveillance audit from a certifying authority), provide data and elements which are evaluated and form the basis for identifying corrective, preventive and improvement actions (e.g. providing specific training for staff, implementing suitable changes in practice and procedures, etc.), thus fostering the continual improvement of the QMS. The implementation and the effectiveness of these actions are monitored by operational departments as well as by the Quality Board. An Annual Quality Review is carried out every year in order to assess the efficiency and effectiveness of the Quality Management System as well as the progress in all continual improvement actions.

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 Principal Directorate Quality Management) emphasize the importance of quality, as a degree to which products' characteristics fulfil the treaty and regulatory requirements. Furthermore, quality data in the form of "Integrated Quality Reports" are presented to all Operational management teams, and are communicated to staff.

(b) Internal communiqués by top management regarding the QMS 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, [gadgets](#), videos, 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.*

The top management of the EPO reviews, on yearly basis, the effectiveness, suitability and adequacy of the QMS. This includes determining the necessary resources and the review of

quality objectives. Quality objectives are communicated to staff via intranet and meetings; their understanding is monitored via internal audits.

21.09 Indicate whether top management or delegated officers of the Authority perform an internal review of the QMS in accordance with paragraphs 21.22-21.25:

- (a) at least once per year (cf. paragraph 21.22);*
- (b) in accordance with the minimum scope of such reviews as set out in Section 8, namely:
to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.22, 21.24(i));
to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.22, 21.24(i));*
- (c) in an objective and transparent way (cf. paragraph 21.22);*
- (d) using input including information according to paragraphs 21.24 (ii)-(vi);*
- (e) recording the results (cf. paragraph 21.25).*

The top management of the EPO reviews, on a yearly basis, the effectiveness, suitability and adequacy of the QMS as summarized in the Annual Quality Report. Inputs to this review include data referring to the monitoring and measurement of PCT products' and services' conformity, and of the PCT Search and Examination process. The results of the top management review are recorded.

2. RESOURCES

21.10 Explanatory note: The granting of ISA/IPEA 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 below, should provide this assurance.

Human resources:

- (i) Provide information about the infrastructure in place to ensure that a quantity of staff:
sufficient to deal with the inflow of work;
which maintains the technical qualifications to search and examine in the required technical fields;
and
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.*
- (ii) Describe the infrastructure in place to ensure that a quantity of appropriately trained/skilled administrative staff is maintained and adapted to changes in workload:
at a level to support the technically qualified staff and facilitate the search and examination process, and
for the documentation of records.*

(i) Human resources planning is done according to a medium term business plan (MTBP) which is annually reviewed depending on operational needs. The President, in accordance with the advice provided by the Management Advisory Committee, approves the MTBP for the Office and reports to the Administrative Council.

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 (vi) below).

Examiners and Formalities Officers 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.

(ii) Staffing levels are fixed by the MTBP (see point (i) above).

Material resources:

(iii) *Describe the infrastructure in place to ensure that appropriate equipment and facilities such as IT hardware and software to support the search and examination process are provided and maintained;*

(iv) *Describe the infrastructure in place to ensure that 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.*

(v) *Describe how instructions:*

to help staff understand and adhere to the quality criteria and standards; and;

to follow work procedures accurately and consistently

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

(iii) Every Examiner and Formalities Officer is equipped with a working place consisting of a computer with access to a platform including all relevant software applications for Classification, Search and Examination, access to the intranet and internet. The applications are maintained by Directorate Application Management DG1, Directorate Application Management DG2 and Principal Directorate Patent Grant Automation (PDPGA).

(iv) 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.

(v) 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 internally via the Single Legal Source (SLS) database. On request they are also distributed on paper form. Staff is kept up to date about the latest adaptations by means of dedicated Practice and Procedure Notes.

Training resources:

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

acquire and maintain the necessary experience and skills; and

are fully aware of the importance of complying with the quality criteria and standards.

Training for Examiners is organized and documented by Directorate Recruitment & Talent Management in DG4 together with Directorate DG1 HR Coordination. Training for Formalities Officers is organized and documented by Directorate Recruitment & Talent Management in DG4 together with PA training team.

The initial training for new examiners is 6-week classroom training. Within the first 2 years of employment examiners receive a total of 59 days of classroom training and are assisted by a tutor in their daily work. Experienced Examiners receive further courses on specific procedural issues 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.

Oversight over resources:

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

to deal with demand; and

comply with the quality standards for search and examination.

Principal Directorate Business Services is in charge for providing estimates of required Examiners.

Senior Management PA is in charge for providing estimates of required Formalities Officers. See points (i) and (ii) above for the compliance with the quality standards.

3. MANAGEMENT OF ADMINISTRATIVE WORKLOAD

21.11 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:

(i) Effective control mechanisms regarding timely issue of search and examination reports to a quality standard as set by the respective Authority; and

(ii) Appropriate control mechanisms regarding fluctuations in demand and backlog management.

DG1 Managers have access to a number of software applications which allow them the monitoring and managing of priorities, timeliness, backlog and requests for search and examination. Principal Directorate Business Services provides monthly reports with operational statistics to Directors and Principal Directors in DG1. In contact Directors meeting this information is shared with Senior Management PA which will take appropriate actions.

4. QUALITY ASSURANCE

21.12 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, including the use of any checklists to verify reports before their issue or for monitoring the quality standard as part of a post-issue review process:

(i) An internal quality assurance system for self-assessment, involving verification, validation and monitoring of searches and examination work:

for compliance with these Search and Examination Guidelines;

for channeling feedback to staff.

(ii) 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.

(iii) A system for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes, and to prevent issues from recurring.

Since 2012, the Quality Board proposes quality objectives according to the quality strategy, , the objectives of which 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, internal audits.

Identification of the key quality issues allows the development of corrective, preventive and/or improvement actions. The effectiveness of the actions is then monitored.

As of 2014, Operational Quality Control in DG1 is carried out according to a procedure called "conformity assurance in search and examination". According to this procedure, a record is kept

of any nonconformity detected, of the re-verification step and of the 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 and is now fully integrated into the Office's Quality Management System.

Quality of classification is monitored via Classification operational quality control (Class-OQC).

5. COMMUNICATION

Inter-Authority communication:

21.13 Explanatory note: Each Authority should provide for effective communication with other Authorities.

(Note: This point is informative. No response is required by the template to paragraph 21.13)

21.14 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.*

Management Representative for Quality is Vice-President DG2: e-mail address VP2@epo.org.

Directorate Quality Support (Principal Directorate Quality Management): e-mail address dqs@epo.org.

Directorate Quality Analysis and Policy (Principal Directorate Quality Management): e-mail address quality@epo.org.

Communication and guidance to users:

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

- (i) An appropriate system for handling complaints and making corrections; taking corrective and/or preventative action where appropriate; and offering feedback to users.*
- (ii) A procedure for: monitoring user satisfaction and perception; and for ensuring their legitimate needs and expectations are met.*
- (iii) 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.*
- (iv) An indication of where and how the Authority makes its quality objectives publicly available for the users*

(i) 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.

An analysis of user 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 by top management for the review of the QMS. Quality issues requiring corrective, preventive or improvement actions are registered in a quality improvement database.

The EPO has established and maintains a documented Corrective Action Procedure to eliminate the causes of nonconformity and to prevent recurrence, as well as a documented Preventive Action Procedure to eliminate the causes of potential nonconformities and to 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 the quality improvement database.

(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 analyzed to detect quality issues and any other cause for dissatisfaction which need to be addressed.

(iii) A Guide for applicants is available on the office's web site under <http://www.epo.org/applying.html>.

(iv) The EPO approach to quality is made public at this link: <http://www.epo.org/about-us/office/quality.html>. On this page the link to publicly available quality indicators can also be found.

21.16 Communication with WIPO and designated and elected Offices:

Describe how the Authority provides for effective communication with the International Bureau and designated and elected offices. In particular describe how the Authority ensures that 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 21.14, above).

6. DOCUMENTATION

21.17 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 21.18).

(Note: This point is informative. No response is required by the template to paragraph 21.17)

21.18 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.*

The Quality Manual and the Manual of procedures is available to all staff via the EPO's intranet site dedicated to quality.

The implemented document control complies with the requirement of the standard under ISO 9001:2008.

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

- (i) the quality policy of the Authority including a clear statement of commitment to the QMS from top management;*
- (ii) the scope of the QMS, including details of and justification for any exclusions;*
- (iii) the organizational structure of the Authority and the responsibilities of each of its departments;*
- (iv) 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;*
- (v) the resources available for carrying out the processes and implementing the procedures; and*
- (vi) a description of the interaction between the processes and the procedures of the QMS.*

These documents are all included in the Quality Manual, either as such, or incorporated by reference to the Manual of Procedures.

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

- (i) a definition of which documents are kept and where they are kept;*
- (ii) results of management review;*
- (iii) training, skills and experience of personnel;*
- (iv) evidence of conformity of processes, resulting products and services in terms of quality standards;*
- (v) results of reviews of requirements relating to products;*
- (vi) the search and examination processes carried out on each application;*
- (vii) data allowing individual work to be tracked and traced;*
- (viii) records of QMS audits;*
- (ix) actions taken re. non-conforming products, e.g. examples of corrections;*
- (x) actions taken re. corrective action;*
- (xi) actions taken re. preventative action; and*
- (xii) search process documentation as set out in Section 7.*

(i) (ii) Relevant documentation and locations are defined in the QMS documentation. Annual Quality Review documentation, including its outcome, is kept in a database administered by the Quality Board.

(iii) Records of staff competencies, development and training received, are kept in a database administered by Principal Directorate Human Resources. Staff has access to these records via FIPS (Finance and Personnel System) and via MyTalent LMS (Learning Management System).

(iv) Certification of the QMS according to ISO 9001:2008 standard for the Patent Process.

(v) Yes, where applicable. The results of reviews are stored in internal databases.

(vi) (vii) 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.

(viii) Records of QMS audits are kept in a central Audit database administered by Principal Directorate Internal Audit.

(ix) 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.

(x) (xi) Records of detected recurrent non-conformities, and the corrective actions taken to address their root cause, are kept in a dedicated database.

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.

(xii) Yes, for details see section 7 below.

7. SEARCH PROCESS DOCUMENTATION

21.21 *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:*

- (vi) *limitation of search and its justification*
- (vii) *lack of clarity of the claims; and*
- (viii) *lack of unity.*

(a)(b) Records of the search process are kept since 1. July 2010. The search record includes the subject, scope and strategy of search (items (i)-(v))

(c) Items (vi)-(viii) are documented in the search report and/or in the written opinion, as appropriate,.

8. INTERNAL REVIEW

21.22 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.

21.23-21.25 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.

The first review according to Chapter 21.10 carried out in 2007 identified actions necessary to ensure the compliance with the set requirements. This finding was communicated to top management in June 2008 and since then annual internal reviews have been carried out with the aim to review the effectiveness of its QMS against organizational goals and quality objectives.

Since the ISO 9001:2008 certification of its QMS, the EPO is committed to carry out the annual internal review, which is furthermore monitored by the ISO certifying authority.

9. ARRANGEMENTS FOR AUTHORITIES TO REPORT TO THE MIA

21.26 There are two stages in the reporting arrangements outlined in Chapter 21: the initial report called for by paragraph 21.26(a), and supplementary annual reports in accordance with paragraph 21.26(b). At the second informal meeting of the Quality Subgroup in Canberra on February 6 and 7, 2012, the Subgroup recommended that, instead of submitting full reports every five years and cumulative updates in the intervening years, Authorities should submit each report in the form of a full report, making the differences from the previous year's report clear, for example using "track changes" or other form of highlighting. The template for the supplementary annual reports is therefore no longer used

The present report show with "tracked changes" the differences with the previous report dated ~~December 13, 2014~~ [November 30, 2015](#).

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