E

WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

ORIGINAL: ENGLISH
DATE: 29NOVEMBER 2019

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 prepared the extension of the scope of certification to the Unitary Patent Protection process. Moreover the Office worked on the transition of the QMS to the new version 2015 of the ISO 9001 standard.

In 2017 the Office finalized the transition of its Quality Management System to the ISO9001:2015 requirements. Certification took place in September 2017. The scope of the certified QMS has not been extended to the Unitary Patent processes since the UPP has not yet entered into force.

In 2018 and 2019 the Office successfully underwent ISO9001:2015 surveillance audits of the Patent Process.

In 2020 the Office will undergo recertification audit under ISO9001:2015 standard.

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 meeting or exceeding its stakeholders' needs and expectations and to remaining 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 with a view to 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 it delivers.

- 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 these 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 President promotes the quality policy and goals within the organisation and to interested parties. In addition, the President ensures that the QMS is maintained and improved in order to achieve the set objectives.

The Management Advisory Committee: The Management Advisory Committee assists the President in overseeing the effectiveness of the EPO and in proposing initiatives and policy changes that have a potential impact on the EPO's activities and reputation.

The Management Representative for Quality (MRQ): The Management Representative for Quality coordinates the maintenance and improvement of the QMS at all levels of the organization, organises the Annual Quality Review to review the effectiveness of the QMS, is responsible for the conformity of the QMS to the ISO 9001 standard, represents the EPO in quality matters to external stakeholders and is responsible for internal communication on the effectiveness of the QMS. This role is assigned to the Vice-President of Directorate General 1.

Each Vice-President: Each Vice-president is responsible for the correct implementation and monitoring of the QMS within the DG.

Quality Board (QB): The Quality Board, chaired by the President or by the Management Representative for Quality by delegation, is made up of the COOs of the three DG1 sectors as well as of Principal Directors representing Human Resources, Internal Audit, Patent Law and Multilateral Affairs, Patent Information and Quality Management. The main functions of the QB comprise the following aspects:

- integrating the QMS into the EPO's management system and,
- recommending and monitoring the implementation of quality improvement measures.

Process owner(s): Process owner(s) are designated for each process described in the QMS. The main responsibilities of the process owners are:

- implementing, reviewing and monitoring effectiveness,
- establishing and maintaining the related QMS documentation and,
- providing feedback to the Quality Board.

Principal Directorate User Support and Quality Management (PDUSQM): The Principal Directorate User Support and Quality Management is dedicated to providing support to the users and to the design, implementation and maintenance of a Quality Management System that covers the processes falling within the scope of the QMS. PDUSQM has a centralised oversight of all quality aspects of the products and services of the EPO Patent Process and the EPO's quality policy.

Directorate Quality Audit: Part of Principal Directorate Internal Audit and Oversight, the Directorate Quality Audit is responsible for conducting internal QMS audits to assess compliance with the requirements of ISO 90001.

Senior and line management: Senior and line management ensure that quality objectives and the quality policy are communicated to staff. When applicable, they translate top level quality objectives into local quality objectives.

Staff: Staff delivers products and services to the users by following the applicable statutory and regulatory requirements, work instructions, QMS processes and other relevant documents. They have the authority and responsibility to initiate action to prevent the occurrence of product or process nonconformity and to identify and report any quality issue.

(c) As of November 2019, Principal Directorate User Support and Quality Management includes Directorates: Directorate Quality Management (responsible for facilitating the policy making process by providing information, data, metrics analysis and recommendations to management and for maintaining the Quality Management System and Directorate User Support (responsible for the First Line User Desk and User Relation Management) , Directorate Patent Procedures Management (responsible for assisting the EPO in all matters of practice and procedure), Directorate Digitisation Support (responsible for digitisation and preparation of publication documents, data exchange and bulk client data requests, paper file creation and central file stores) and Directorate Classification and Documentation (acting as the authority and centre of competence for all classification and prior-art documentation matters).

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)	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 to the relevant staff at 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 aligned with 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	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
		(e)	recording the results	✓		
21.10			Risk and opportunities are addressed that can affect the QMS and the conformity of search and examination	✓		
21.13			Arrangements for establishing risk-based practices to	✓		
	(i)	(a)	understand issues that affect its ability to achieve intended results of the QMS	✓		
		(b)	understand the needs and expectations of interested parties	✓		
	(ii)		identify risks and opportunities related to the performance of the QMS as a basis for planning	✓		
	(iii)		plan and implement actions to address risks and opportunities	✓		
	(iv)		check the effectiveness of the actions taken	✓		
	(v)		continuously update risks and opportunities.	✓		
21.15			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 technical 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 of records	✓		
	(iii)		Ensuring appropriate equipment to carry out S&E	✓		
	(iv)		Ensuring documentation according to Rule 34	✓		
	(v)	(a)	Instructions to help staff understand and act according to the quality criteria and standards	✓		
		(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	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
		(b)	System in place for monitoring resources required to comply with the quality standards in S&E	✓		
21.16	(i)		Control mechanisms to ensure timely issue of S&E reports	✓		
	(ii)		Control mech. regarding fluctuations in demand and backlog	✓		
21.17	(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, eliminate the causes and prevent issues from recurring	✓		
21.19		(a)	Contact person helping identify best practice between Authorities	✓		
		(b)	Contact person fostering continual improvement	✓		
		(c)	Contact person providing for effective communication with other Authorities for feedback and evaluation	✓		
21.20	(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	✓		
			Indication where and how the Authority makes its quality objectives publicly available	✓		
21.21			Established communication with WIPO and designated and elected Offices	✓		
21.22			QMS of Authority clearly described and documented	✓		
21.23		(a)	Material making up the reference of quality procedures and processes for staff and management has been prepared and distributed	✓		
		(b)	Media available to support the reference material	✓		
		(c)	Document control measures are taken	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
21.24			Items which should be documented in the reference of quality procedures and processes	✓		
	(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.	✓		
21.25	(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	✓		
21.26	(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	✓		
	(viii)		Records about lack of clarity of the claims	✓		
	(ix)		Records about lack of unity	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
21.27			Report on its own internal review processes	✓		
21.28-21.30			Additional information on further inputs to its internal reviews	✓		
21.31			Initial report called for by paragraph 21.31	✓		

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. The Annual Quality Review is chaired by the President who sets the new Quality objectives, approves quality action plans and ensures adequacy of the QMS and the Quality Policy in view of the context of the organisation and the requirements of the relevant interested parties.

An Intermediate Quality Review is held in the middle of the quality year to assess progress in the quality action plan and achievement of the quality objectives and reviews the course of actions for the second half of the quality year. The Intermediate Quality review is chaired by the President.

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 User Support and 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, eLearning modules)

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 regular 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, meetings as well as part of the regular performance management framework; 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. RISK-BASED PRACTICES

21.11 Explanatory note: Each Authority should establish its own risk-based practices to enable the Authority to determine factors that could cause operational processes and its quality management system to deviate from requirements or planned results, to put in pace preventive controls to minimize negative effects, and to make use of opportunities as they arise.

21.12 Explanatory note: It is open to each Authority to set up its own arrangements to determine the effect of uncertainty on objectives. Paragraph 21.13 provides a guide to the basic components of risk-based practices as an element of QMS. There is no requirement for formal methods of risk management or a documented risk management process.

(Note: These points are informative. No response is required by the template to paragraphs 21.11 and 21.12).

21.13 Arrangements for establishing risk-based practices

Provide information on the arrangements that your Authority has made to:

(i) (a) understand issues that affect its ability to achieve intended results of the QMS, and

(b) understand the needs and expectations of interested parties;

(ii) identify risks and opportunities related to the performance of the QMS as a basis for planning;

(iii) plan and implement actions to address risks and opportunities;

(iv) check the effectiveness of the actions taken; and

(v) continuously update risks and opportunities.

21.14 Explanatory note: All processes of the QMS present differing levels of risk in terms of the Authority's ability to meet its objectives, and the effects of uncertainty are not the same for all Authorities. Each Authority is responsible for the actions it decides to take to address risks and opportunities.

(Note: This point is informative. No response is required by the template to paragraph 21.14).

The Quality Board is responsible for assessment and monitoring of risks and opportunities based on the feedback from the respective process owners. The Quality Board implements preventive and/or improvement actions in order to address identified risks and/or opportunities.

3. 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 Business Intelligence Technology Unit.

(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. The maintenances and the quality of the stored data is ensured by the Documentation department.

(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 and Formalities Officers is organized and documented by Directorate Talent Management in DG4.

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.

Directorate Business Analysis and Planning under theresponsibility of the Vice-President Patent Granting Process is in charge for providing estimates of required Examiners and Formalities Officers.

See points (i) and (ii) above for the compliance with the quality standards.

4. 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. Directorate Business Analysis and Planning provides monthly reports with operational statistics to Directors and Principal Directors in DG1.

5. 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” (CASE). 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 Formalities Officers Operational Quality Control has been improved in 2014 to better suit business needs and is now fully integrated into the Office’s Quality Management System (OQC-FO).

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

6. 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 DG1: e-mail address VP1@epo.org.

Principal Directorate User Support and 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 Management 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 website 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, as well as of the Intermediate Quality Report which are the documents 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) The user satisfaction survey covering patent granting process is being redesigned following consultations with users.

(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/services-and-activities/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 Directorate Quality Management (see 21.14, above).

7. 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 are 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 9001:2015.

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 process documents.

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. The Annual Quality Review and Intermediate Quality Review as well as Quality Board meetings documentations, including their 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 9001:2015 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 owners. The EPO has an electronic system in place that informs an entrusted Process Owner when a given 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.

8. 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.

9. 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 EPO carries out its internal review as internal audits under ISO9001:2015 standard.

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

10. 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 shows with "tracked changes" the differences with the previous report dated November 30, 2018.

[End of document]