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Patent Cooperation Treaty (PCT)

Common Quality Framework for International Search and Preliminary Examination

REPORT ON QUALITY MANAGEMENT SYSTEMS

prepared by the 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 has been actings as an International Searching Authority and International Preliminary Examination Authority since 1978.

The quality of the products and services delivered by the EPO is recogniszed across the patent world, and the EPO ~~management~~ is committed to maintaining and even enhancinge ~~this~~ ~~e Office's~~ leading position~~. This Office aims to achieve this by sustaining~~ through a strong and effective ~~commitment~~ dedication to quality at all levels.

In 2014, the EPO's qQuality mMmanagement sSystem (QMS) ~~of the Office has been~~ was certified to ISO 9001:2008 for the patent granting process, which includes ~~the~~ PCT sSearch and eExamination work.

In 2015, the QMS has extended the scope of certification to pPatent iInformation and post-grant activities. As a result, the new scope of the ISO 9001:2008 certified QMS is the pPatent pProcess.

In 2016, the EPOffice undertook preparationsed the to extendsion of the scope of certification to the uUnitary pPatent pProtection process. Moreover Itthe Office also worked embarked on the transition of the QMS to the new version 2015 version of the ISO 9001 standard.

In 2017, the EPOffice finaliszed the transition of its Quality Management System to the ISO 9001:2015 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 2019, the EPOffice adopted its Strategic Plan 2023 (SP2023), in which it set out a vision for its future aiminged at providing a prosperous futureoutlook for European innovation and a strong patent network. One of the key initiatives under SP2023 Key Initiatives aims at is to enhanceing process efficiency. The EPOffice intends to extend the ISO 9001 certification to all areas across the organisationnot covered till nowof the Office , and obtain other ISO certifications.

In 2020, Principal Directorate Corporate Governance Service (PD CGS) in DG0 was established in Directorate-General Patent Granting Process (DG 0). Within PD CGS, Directorate Quality and Risk Management within CGS is entrusted with the tasks of extending the application of the ISO 9001 standard to all areas within the organisation the whole Office and incorportegrating all EPO's management systems into an integrated management framework.

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

In 2020, the EPO's patent process QMSffice successfully will undergowentpassed a recertification audit of its Patent Process QMS under the ISO 9001:2015 standard, and its Occupational Health and Safety management system also it obtained ISO 45001:2018 certification for EPO's Occupational Health and Safety management system.

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 EPO's Quality Policy of the EPO is available communicated internally (e.g. intranet, posters, gadgetsetc.) and published on EPO the website at http://www.epo.org/about-us/office/quality/policy.htmlepo.org/about-us/services-and-activities/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 the global quality leader inof 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 it 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) The President: tThe President has the overall responsibility for the QMS. He establishes the Quality Policy and quality objectives to support the QMS. The President promotes the Qquality Ppolicy and quality goals within the organisation and to with 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 (MAC): tThe 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): uUntil June 2020, tThe Management Representative for Quality co-ordinateds the maintenance and improvement of the QMS at all levels of the organiszation, including the organisingationes of the aAnnual qQuality rReview. to review the effectiveness of the QMS, The MRQ was alsois responsible for the complianceformity of the QMS to with the ISO 9001 standard, representeds the EPO oin quality matters to with external stakeholders and is was responsible for internal communication on the effectiveness of the QMS. Since July 2020, tThe isco-ordination role is assigned to the PD Vice-President of Directorate-General 1Principal Directorate Corporate Governance Service, more specifically Directorateirectorate Quality and Risk Management. The EPOffice operates withtakes a federated approach ensuring each area takes responsibility for the maintenance and improvements of the QMS as it applies to their process area.

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

The Quality Board (QB): uUntil June 2020, The the Quality Board, chaired by the President or by the Management Representative for Quality by delegation, was responsible for:

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

It wasis made up of the chief operating officers (COOs) of the three DG 1 sectors as well as of pPrincipal dDirectors or directors representing Corporate Governance Service, Human ResourcesPeople, Internal Audit, Patent Law and Multilateral Legal Affairs, Patent Information Knowledge and Quality Management.

Since July 2020, the Quality Board was integrated into the EPO's new integrated management IMS governance structure, of the EPO with the President maintaining the overall responsibility and the MAC supporting him. Operational elements of the management systems have been integrated into the Executive Operationsal Committee (EOC) in under the chairmanship of the Vice-President DG 1 (the Patent Granting Process or (PGP). 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): pProcess 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 Boardrespective appropriate MAC members.

Directorate Quality and Risk Management (QRM) within PD Principal Directorate Corporate Governance Service (CGS) is dedicated to maintaining the EPO''s QMS and to designing a single integrated management framework bringing together all of the EPO''s management systems. QRM has a centraliszed oversight of all of the EPO''s corporate quality aspects of the EPO and the EPO''s Qquality Ppolicy.

Principal Directorate Quality, Business and User Services User Support and Quality Management (PDUSQMPD QBUS): PD QBUS The Principal Directorate User Support and Quality ManagementQuality, Business and User Support is dedicated to providing support to the users and to the design, implementation and maintenance of a the PGP Quality Management System that covers the Patent Granting ingprocesses Processes (PGP)falling within the scope of the QMS. PD QBUSQM has an centralised oversight of all quality aspects of the products and services of the EPO's p Patent pProcess. and the EPO's quality policy.

Directorate Quality Audit: within Part of Principal Directorate Internal Audit and Oversight, the Directorate Quality Internal Audit is responsible for conducting internal QMS audits to assess compliance with the requirements of ISO 9000001., while the Directorateirectorate Quality Audit is responsible for carrying our product audits.

Senior and line managersment: s Senior and line managersment ensure that quality objectives and the Qquality Ppolicy are communicated to staff. When applicable, they translate top level quality objectives into local quality objectives.

Staff: sStaff deliverss 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 September 20192020, Principal Directorate Quality, Business and User Support Services (PD QBUS) and Quality Management includes the following Ddirectorates:

1. Directorate Operational Quality and Risk Management (responsible for facilitating the policy making process by providing information, data, metrics analysis and recommendations to management and for maintaining the Quality Management Systemmanaging the quality and risk management system, quality assurance and

metrics analysis for the p~~P~~atent g~~G~~rantingin~~g~~ p~~P~~rocess, ~~and~~ as well as for complaints handling), ~~and~~

2. ~~-~~Directorate User ~~User Support~~Enquiries and Intelligence (~~responsible for the First Line User Desk and User Relation Management~~which is the first and direct point of contact ~~to~~ for the user community)~~,~~
3. Directorate P~~atent Procedures Management~~rocedural Support (responsible for assisting the EPO in all matters of practice and procedure by providing analysis, consultation, communication and instructions; it is also responsible for digitisation and preparation of publication documents, data exchange and bulk client data requests, paper file creation and central file stores)~~, 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~~
~~1.~~4. ~~-~~Directorate Prior Art and 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	✓		
		(e)	recording the results	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
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	✓		
		(b)	System in place for monitoring resources required to comply with the quality standards in S&E	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
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 channelling 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	✓		
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	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
	(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	✓		
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 measurement~~s~~ of ~~the~~ processes, ~~monitoring and measurements of~~ product~~s'~~ and service~~s'~~ conformity, ~~the monitoring of~~ user~~s'~~ satisfaction and~~,~~ the results ~~from~~ of 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~~operational governance structures, e.g. the EOC and the MAC.

An a~~A~~nnual q~~Q~~uality r~~R~~eview is carried out every year ~~in order~~ to assess the efficiency and effectiveness of the Q~~uality~~ M~~anagement~~ S~~ystem~~ as well as the progress ~~in~~ of all continual improvement actions. The a~~A~~nnual q~~Q~~uality r~~R~~eview is chaired by the President, who sets the new q~~Q~~uality objectives, approves quality action plans and ensures ~~adequacy of~~ that the QMS and the Quality Policy are fit for purpose in view of ~~the context of~~ the organisation and the requirements of the relevant interested parties.

An i~~I~~ntermediate q~~Q~~uality r~~R~~eview is held in the middle of the quality year to assess progress ~~in~~ under the quality action plan and achievement of the quality objectives, and to review~~s~~ the ~~course of~~ actions planned for the second half of the quality year. The i~~I~~ntermediate q~~Q~~uality 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)~~ emphasi~~s~~ze the importance of quality~~,~~ as an indicator of the degree ~~to~~ which product~~s'~~ characteristics fulfil the T~~t~~reaty and regulatory requirements. ~~Furthermore, q~~Quality data ~~in the form of "Integrated Quality Reports" are~~ is presented to all o~~O~~perational management teams~~,~~ in the form of "integrated quality reports" and then ~~are~~ communicated to staff.

(b) Internal communiqués ~~by~~ from top management are published internally on a regular basis ~~regarding~~ on ~~the~~ QMS implementation, the yearly quality objectives and results ~~achieved in~~ from the previous year ~~are published internally on a regular basis~~. Further means of communication ~~means~~ are used to address quality matters a~~t~~o all levels of the organi~~s~~zation (e.g. Quality ~~intranet~~ webpage~~quality site~~, posters, flyers, ~~gadgets,~~ videos, workshops, training/awareness sessions, e-~~l~~Learning 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 EPO's top management regularly of the EPO reviews, on regular basis, the effectiveness, suitability and adequacy of the QMS. This includes determining the necessary resources and the reviewing of quality objectives. Quality objectives are communicated to staff via the intranet, at meetings as well as within the part of the regular performance management framework; their understanding staff awareness 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 EPO's top management of the EPO annually reviews, on a yearly basis, the effectiveness, suitability and adequacy of the QMS as summarized indicated in the aAnnual qQuality rReport. Inputs to tThis review include incorporates data relatferring to the monitoring and measurement of PCT products' and services' conformity, and of the PCT sSearch and eExamination 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 minimisze 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).

In 2020, the EPO started to implement a Ccorporate rRisk mManagement (CRM) framework based on the risk management guidelines of the ISO 3100000 and the Committee of Sponsoring Organizsations and the Treadway Commission's (COSO) risk management guidelines. PD The Principal Directorate Corporate Governance Service maintainsoversees the overall risk management process for the organisation, evaluates its application and suggests improvements. The EPO's's rRisk mManagement framework is based on a federated approach, which means that each department is managesing their its own risks, but all risks are centrally tracked in a single corporate risk register , which that is shared among accessible to all EPO's departments and used to report and manage risks and opportunities. The single central corporate risk register ensures awareness and transparency and provides an opportunity for different departments to collaborate when mitigating similar or the same or similar risks or to exploiting opportunities together.

PD CGS oversees the correct application of the processes related to belonging to the corporate risk management framework. It supports the President in establishing and maintaining the policiesy related on to the level of risk the EPO is willing to take (risk appetite). CGS It manages the corporate risk register and prepares reports on risk management. It also supports the local risk management teams and audit processes and procedures related to the risk management.

Risk management and especially the identification of risks is an integral part tof the day-to-day tasks work of each every EPO's staff member.

At the heart of the EPO rRisk mManagement framework is a network of risk practitioners operating throughout all DGs and , which is maintained and stimulatedguided by PD CGS.

Risk practitioners use their expertise to facilitate the risk management process. They help to identify risks, assess them, recordgister them in the EPO risk register and follow up with response plans.

Risks, opportunities and issues identified are assessed to understand their impacts on the EPOffice, departments and the respective abilityies to meet the the desired objectives, needs and expectations of interested parties.

PD CGS reports regularly to the EPO top management 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.on risks and opportunities requiring its attention. Risk reports are also provided to shared with the Directorate Internal Audit and Oversight for the purpose of internal audit planning.

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 tobased on a medium- term business plan (MTBP) which is annually reviewed annually 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 on it to the Administrative Council.

Examiners and fFormalities oOfficers are recruited according to in accordance with the skills as requirementsd by specified in the particular relevant job descriptions. They also receive on-the-job training during their career at the EPO (see point (vi) below).

Examiners and fFormalities oOfficers at the EPO must be able to work in all three official EPO languages of the Office. To that purpose end, the EPOffice 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 Eexaminer and fFormalities oOfficer is equipped with a workstationing place consisting of a computer with access to a platform including hosting all relevant software applications for cClassification, sSearch and eExamination, as well as with access access to the intranet and internet. The applications are maintained by the Business Intelligence Information Technology uUnit. All eExaminers and fFormalities oOfficers are able to telework. The tTeleworking scheme provides necessary hardware and software tools allowing equal access to all platforms mentioned above via a standard iInternet connection.

(iv) Every eExaminer has access to internal and external databases in accordance to with 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 Information Processing department.

(v) The relevant legal texts and instructions (e.g. PCT, EPC, Guidelines and iinternal iinstructions) 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 areis 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 eExaminers and fFormalities oOfficers is organiszed and documented by DG 4's Directorate Talent Management in DG4.

The initial training for new examiners is sixa 6-weeks of classroom training. Within the first 2 two years of employment examiners receive a total of 59 days of classroom training and are assisted by a tutor in their daily work. Experienced eExaminers receive further courses on specific procedural issues aspects of the patent granting procedure.

Formalities oOfficers receive an initial two to four2 4 weeks of classroom training, depending according toon the procedures they are employed recruited for, and are supported by a coach whenever needed. Afterwards they receive training on additional procedures either on the job or in a specificed classroom training module, followed by coach assistance at the discretion of their 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 the responsibility of the Vice-President DG 1 (Patent Grantinging Process) is in charge for providing estimates of required eExaminers and fFormalities oOfficers.

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.

DG 1 mManagers have access to a number of software applications which allow them the to monitoring and manageing of priorities, timeliness, backlog and requests for search and examination. The Directorate Directorate Business Analysis and Planning unit within PD the Vice-P resident DG1 Office provides monthly reports with operational statistics to Directors and Principal Directors inthe DG 1 management team.

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 channelling 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 BoardPrincipal Directorate Quality, Business and User Services proposes quality objectives according to the quality strategy. These , the objectives of which are endorsed by top management.

Quality-related results are presented to operational management teams throughby the Qquality lLead dDirectors (, one per sector), and who reporting to the DG 1 Quality Committee. 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 for the development of corrective, preventive and/or improvement actions. The effectiveness of the actions is then monitored.

As of Since 2014, oOperational qQuality cControl in DG 1 is carried out according to a the CASE procedure called (C"conformity Aassurance in for Ssearch and Eexamination" (CASE). According to this procedure, a record is kept of any nonconformity detected, of the re-verification step and of the corrective actionon which is taken before releasing the product.

The methodology applied for carrying out fFormalities oOfficers' oOperational qQuality cControl whas been improved in 2014 to better suit business needs and is now fully integrated into the Office's EPO's Quality Management System (OQC-FO).

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

7. 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 DG1The President: e-mail addressemail to presidentVP1@epo.org.

Principal Directorate Corporate Governance Service and Principal Directorate Quality, Business and User Support Servicesand Quality Management: e-mail address:to 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 Operational Quality and Risk 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 may be involved in the complaint handling procedure (e.g. for providing feedback and if required for taking suitable corrective and/or preventive actions). As oSince f 01 January .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 provided in the aAnnual qQuality rReport, as well as and of the iIntermediate qQuality rReport, both of which are the documents used by top management for the review of the QMS. Quality issues requiring corrective, preventive or improvement actions are recordedgistered in a quality improvement database.

The EPO has established and maintains a documented cCorrective aAction pProcedure to eliminate the causes of nonconformity and to prevent recurrence, as well as a documented Preventive Action Proceduretogether with a list of preventive actions and risk management 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 the patent granting process is being redesigned following user consultations with users.

(iii) A gGuide for applicants is available on the office's EPO web site under at http://www.epo.org/applying.htmlepo.org/applying.html.

(iv) The EPO approach to quality is made publishedc on the website at t this link: epo.org/about-us/services-and-activities/quality/policy.htmlhttp://www.epo.org/about-us/services-and-activities/quality.html. On this page the A link to publicly available quality indicators can also be found on the website.

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 A number of EPO departments are of the EPO are designated to regularly represented attend at WIPO meetings. Feedback from WIPO is addressed by the relevant departments; in particular, feedback related to product quality matters is addressed by Directorate Operational Quality and Risk 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 m~~M~~anual of procedures are available to all staff via the EPO~~'~~s Quality webpage~~intranet site dedicated to quality~~.

The ~~implemented~~ document control measures taken comply~~ies~~ with the requirements 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 organis~~z~~ational 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 a~~A~~nnual q~~Q~~uality r~~R~~eview and i~~I~~ntermediate q~~Q~~uality r~~R~~eview as well as Q~~uality B~~o~~ard~~ meeting~~s~~ ~~documentation~~minutes (~~s,~~ including ~~their~~ outcome~~s~~), ~~is~~ are kept in a database administered by the Q~~uality B~~o~~ard~~.

(iii) Records of staff competencies, development and training received~~,~~ are kept in a database administered by P~~rincipal D~~i~~rectorate Human Resources~~People. Staff ha~~ve~~s~~ access to these records via FIPS (Finance and Personnel System) and via MyTalent LMS (Learning Management System).

(iv) QMS c~~C~~ertification ~~of the QMS~~ according to ISO 9001:2015 ~~standard~~ for the p~~P~~atent p~~P~~rocess.

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

(vi) (vii) ~~The whole~~ All documentation ~~on~~ relating to the ~~all~~ search and examination processes carried out on an application ~~makes up the content~~ is collated in ~~of~~ the electronic file and is ~~centrally~~ stored centrally.

(viii) Records of QMS audits are kept in a central a~~A~~udit database administered by P~~rincipal D~~i~~rectorate~~ Internal Audit and Oversight.

(ix) The EPO has two mechanisms f~~t~~or detecting non~~-~~conforming products in search and examination during the PCT phase; i.e. checks by the d~~D~~irector and checks by a different examiner. ~~Detected N~~non~~-~~conformities detected and ~~the respective~~ corrective action takens ~~of the non-conforming products~~ are recordgistered in a dedicated database and discussed with the original ~~entrusted~~ examiner.

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

Process performance is monitored using k~~K~~ey p~~P~~erformance i~~I~~ndicators (KPIs) which are specifically defined by the process owners. The EPO has an electronic system in place that informs a~~n entrusted P~~process o~~O~~wner when a given KPI falls below a threshold value. This allows the p~~P~~rocess o~~O~~wner to take suitable preventive action~~s~~ t~~f~~o~~r~~ ensure~~ing~~ that the objectives set for the process are met. Records of preventive action~~s~~ 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) Search r~~R~~ecords ~~of the search process are~~ have been kept since 1 July 2010 and ~~. The search record~~ include~~s~~ the subject, scope and strategy of the 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 ISO 9001:2015 ~~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~~ assess the effectiveness of ~~its~~ the QMS against organis~~z~~ational goals and quality objectives.

Since achieving ~~the~~ ISO 9001 certification of its QMS, the EPO has~~is~~ committed to carrying 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~~ uses revision marks to "track~~ed~~ changes that have been made to " ~~the differences with~~ the previous report dated 29 November ~~30~~29, 201~~98~~.

[End of document]