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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)

In this introduction, each Authority should include a summary of all changes to their quality management system that have taken place since the previous report on their Quality Management System, and any other matters considered to be interest in relation to quality management.

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. Authorities may include process charts if this would facilitate the understanding of an aspect of the report.

The European Patent Office has been acting as an International Searching Authority and International Preliminary Examination Authority since 1978.

The quality of the products and services delivered by the EPO is recognised across the patent world, and the EPO is committed to maintaining and even enhancing this leading position through a strong and effective dedication to quality at all levels.

In 2014, the EPO's quality management system (QMS) was certified to ISO 9001:2008 for the patent granting process, which includes PCT search and examination work.

In 2015, the QMS 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 EPO undertook preparations to extend the scope of certification to the unitary patent protection process. It also embarked on the transition of the QMS to the new 2015 version of the ISO 9001 standard.

In 2017, the EPO finalised the transition of its QMS to the ISO 9001:2015 requirements. Certification took place in September 2017.

In 2019, the EPO adopted its Strategic Plan 2023 (SP2023), in which it set out a vision for its future aimed at providing a prosperous outlook for European innovation and a strong patent network. One of the key initiatives under SP2023 is to enhance process efficiency. The EPO intends to extend ISO 9001 certification to all areas across the organisation and obtain other ISO certifications.

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

In 2020, the EPO's patent process QMS successfully passed a recertification audit under the ISO 9001:2015 standard and its Occupational Health and Safety (OHS) management system also obtained ISO 45001:2018 certification.

In 2021, the EPO's patent process QMS and its OHS management system successfully passed a surveillance audit under the ISO 9001:2015 and ISO 45001:2018 standard, respectively.

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 is communicated internally (e.g. intranet, posters, etc.) and published on the website at epo.org/about-us/services-and-activities/quality/policy.html.

The Quality Policy which presently is in place reads ~~is~~ as follows:

The EPO is dedicated to meeting or exceeding its stakeholders' needs and expectations and to remaining the global quality leader in 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 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.

It is expected that the Quality ~~é~~Polic~~a~~y w~~e~~ill be replaced by ~~the~~a Patent Quality Charter towards the end of 2022.

(b) The President: the President has overall responsibility for the QMS. He establishes the Quality Policy and quality objectives to support the QMS. The President promotes the Quality Policy and quality goals within the organisation and 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): the MAC 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): until June 2020, the MRQ co-ordinated the maintenance and improvement of the QMS at all levels of the organisation, including organising the annual quality review. The MRQ was also responsible for the compliance of the QMS with the ISO 9001 standard, represented the EPO on quality matters with external stakeholders and was responsible for internal communication on the effectiveness of the QMS. Since July 2020, the co-ordination role is assigned to the PD CGS, more specifically Directorate Quality and Risk Management. The EPO takes a federated approach ensuring each area takes responsibility for the maintenance and improvement of the QMS as it applies to their process area.~~

The EPO takes a federated approach ensuring each area takes responsibility for the maintenance and improvement of the QMS as it applies to their process area. The role ~~to~~of coordinat~~e of~~ing the maintenance and improvement of the QMS at all levels of the organisation is assigned to ~~the~~ PD CGS, more specifically Directorate Quality and Risk Management.

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

~~The Quality Board (QB): until June 2020, the QB, chaired by the President or by the MRQ 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 was made up of the chief operating officers (COOs) of the three DG 1 sectors as well as of principal directors or directors representing CGS, People, Internal Audit, Legal Affairs, Patent Knowledge and Quality Management.

Since July 2020, the QB was integrated into the EPO's new integrated management governance structure, with the President maintaining overall responsibility and the MAC supporting him. Operational elements of the management systems have been integrated into the Executive Operations Committee (EOC) under the chairmanship of the Vice-President DG 1 (Patent Granting Process or PGP).The EPO's integrated management governance structure includes the President to, who maintains overall responsibility for the QMS and, with the MAC supporting him. Operational elements of the management systems have been integrated into the Executive Operations Committee (EOC) under the chairmanship of the Vice-President DG 1 (Patent Granting Process or PGP) while including all internal stakeholders. This includes also 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 appropriate MAC members.

Directorate Quality and Risk Management (QRM) within PD 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. It is further responsible for conducting internal QMS audits to assess compliance with the requirements of ISO 9001. QRM has centralised oversight of all of the EPO's corporate quality aspects and the EPO's Quality Policy.

Principal Directorate Quality and Practice Harmonisation (PD QPH) maintains the ISO 9001:2015 QMS of the Patent Grant Process, promotes harmonisation and consistent practices as well as supports continual improvement of operational quality.

Principal Directorate Customer Journey and Key Account Management brings together services to support customers in their journey throughout the Patent Grant Process. Moreover, it allows gaining insight into the needs of the users of the European Patent System so that we can serve them better.

Principal Directorate Quality and Practice Harmonisation, Business and User Services (PD QBUS): PD QBUS is washas been in 2021 dedicated in 2021 to providing support to users and to the design, implementation and maintenance of the PGP QMS. PD QBUS hads oversight of all quality aspects of the products and services of the EPO's patent process. In the new structure

Directorate Quality Audit,: within PD Internal Audit and OversightProfessional Standards,, Directorate Internal Audit is responsible for conducting internal QMS audits to assess compliance with the requirements of ISO 9001, while Directorate Quality Audit is responsible for carrying out our product audits. Since October 2021, the search audit has been extended to include search opinions.

Senior and line managers: senior and line managers 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 deliver 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) A new organisational structure as of 1 April 2022 has been established for the Patent Grant Process with the following Principal Directorates:.

(c) As of September 2020, PD QBUS includes included the following directorates:

1. Principal Directorate Operational Quality and Risk Management (responsible for managing the quality and risk management system, quality assurance and metrics analysis for the patent granting process, as well as for complaints handling),Quality and Practice Harmonisation
2. Principal Directorate User Enquiries and Intelligence (first and direct point of contact for the user community)Customer Journey and Key Account Management
3. Principal Directorate Procedural 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)Digital Change and Business Transformation, Delivery of Strategic Plan 2023
- Principal Directorate Prior Art and Classification (acting as the authority and centre of competence for all classification and prior-art documentation matters).Business Planning and Performance
- Principal Directorate Opposition and Central Formalities

4. Chief Operating Officer Operationsonas of thein 1 April 2022.

The graphical representation of the EPO structure can be found on the EPO website (https://www.epo.org/about-us/at-a-glance.html).

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	ü		
		(b)	Identified roles and names for QMS responsibility	ü		
		(c)	Organizational chart available	ü		
21.05			Established compatibility of QMS with Chapter 21	ü		
21.06		(a)	Mechanisms to ensure effectiveness of the QMS	ü		
		(b)	Control of the continual improvement process	ü		
21.07		(a)	Communication of management about this standard to staff	ü		
		(b)	The PCT Guidelines are in line with the Authority's QMS	ü		
21.08		(a)	Management reviews take place	ü		
		(b)	Quality objectives are reviewed	ü		

Chapter 21 requirement				Extent of compliance		
				full	part	no
		(c)	Communication of quality objectives to the relevant staff at the Authority	ü		
21.09		(a)	Performance of a yearly internal review of the QMS in/to	ü		
		(b)	determine the extent to which the QMS is aligned with Chapter 21	ü		
			determine the extent to which S&E complies with PCT Guidelines	ü		
		(c)	an objective and transparent way	ü		
		(d)	using input incl. information according paragraph 21.24	ü		
		(e)	recording the results	ü		
21.10			Risk and opportunities are addressed that can affect the QMS and the conformity of search and examination	ü		
21.13			Arrangements for establishing risk-based practices to	ü		
	(i)	(a)	understand issues that affect its ability to achieve intended results of the QMS	ü		
		(b)	understand the needs and expectations of interested parties	ü		
	(ii)		identify risks and opportunities related to the performance of the QMS as a basis for planning	ü		
	(iii)		plan and implement actions to address risks and opportunities	ü		
	(iv)		check the effectiveness of the actions taken	ü		
	(v)		continuously update risks and opportunities	ü		
21.15			Assurance to monitor and adapt to actual workload	ü		
	(i)		Infrastructure in place to ensure that a quantity of staff	ü		
		(a)	sufficient to deal with the inflow of work	ü		
		(b)	which maintains technical qualifications to S&E in all technical fields	ü		
		(c)	which maintains the language facilities to understand languages according to Rule 34	ü		
	(ii)		Infrastructure to provide a quantity of skilled administrative staff	ü		
		(a)	at a level to support the technically qualified staff	ü		
		(b)	for the documentation of records	ü		
	(iii)		Ensuring appropriate equipment to carry out S&E	ü		
	(iv)		Ensuring documentation according to Rule 34	ü		

Chapter 21 requirement				Extent of compliance		
				full	part	no
	(v)	(a)	Instructions to help staff understand and act according to the quality criteria and standards	ü		
		(b)	Instructions to follow work procedures accurately and they are kept up to date	ü		
	(vi)	(a)	Training and development program to ensure and maintain necessary skills in search and examination	ü		
		(b)	Training and development program to ensure awareness of staff to comply with the quality criteria and standards	ü		
	(vii)	(a)	System in place for monitoring resources required to deal with demand	ü		
		(b)	System in place for monitoring resources required to comply with the quality standards in S&E	ü		
21.16	(i)		Control mechanisms to ensure timely issue of S&E reports	ü		
	(ii)		Control mech. regarding fluctuations in demand and backlog	ü		
21.17	(i)		Internal quality assurance system for self-assessment	ü		
		(a)	for compliance with S&E Guidelines	ü		
		(b)	for channelling feedback to staff	ü		
	(ii)		System for measurement of data and reporting for continuous improvement	ü		
	(iii)		System for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes and prevent issues from recurring	ü		
21.19		(a)	Contact person helping identify best practice between Authorities	ü		
		(b)	Contact person fostering continual improvement	ü		
		(c)	Contact person providing for effective communication with other Authorities for feedback and evaluation	ü		
21.20	(i)	(a)	Appropriate system for handling complaints	ü		
		(b)	Appropriate system for taking preventive/corrective actions	ü		
		(c)	Appropriate system for offering feedback to users	ü		
	(ii)	(a)	A procedure for monitoring user satisfaction & perception	ü		
		(b)	A procedure for ensuring their legitimate needs and expectations are met	ü		
	(iii)		Clear and concise guidance on the S&E process for the user	ü		
			Indication where and how the Authority makes its quality objectives publicly available	ü		

Chapter 21 requirement				Extent of compliance		
				full	part	no
21.21			Established communication with WIPO and designated and elected Offices	ü		
21.22			QMS of Authority clearly described and documented	ü		
21.23		(a)	Material making up the reference of quality procedures and processes for staff and management has been prepared and distributed	ü		
		(b)	Media available to support the reference material	ü		
		(c)	Document control measures are taken	ü		
21.24			Items which should be documented in the reference of quality procedures and processes	ü		
	(i)		Quality policy of the Authority and commitment to QMS	ü		
	(ii)		Scope of QMS	ü		
	(iii)		Organizational structure and responsibilities	ü		
	(iv)		the documented processes are carried out in the Authority	ü		
	(v)		Resources available to carry out processes and implementing the procedures	ü		
	(vi)		a description of the interaction between the processes and the procedures of the QMS.	ü		
21.25	(i)		Records which documents are kept and where they are kept	ü		
	(ii)		Records of results of management review	ü		
	(iii)		Records about training, skills and experience of staff	ü		
	(iv)		Evidence of conformity of processes	ü		
	(v)		Results of reviews of requirements relating to products	ü		
	(vi)		Records of the S&E process carried out on each application	ü		
	(vii)		Record of data allowing individual work to be tracked	ü		
	(viii)		Record of QMS audits	ü		
	(ix)		Records on actions taken re. non-conforming products	ü		
	(x)		Records on actions taken re. corrective actions	ü		
	(xi)		Records on actions taken re. preventive actions	ü		
	(xii)		Records referring to search process documentation	ü		
21.26	(i)		Recording of the databases consulted during search	ü		
	(ii)		Recording of keywords, combination of words and truncations during search	ü		
	(iii)		Recording of the languages used during search	ü		

Chapter 21 requirement				Extent of compliance		
				full	part	no
	(iv)		Recording of classes and combinations thereof consulted during search	ü		
	(v)		Recording of a listing of all search statements used in databases consulted	ü		
	(vi)		Records about other information relevant to the search	ü		
	(vii)		Records about limitation of search and its justification	ü		
	(viii)		Records about lack of clarity of the claims	ü		
	(ix)		Records about lack of unity	ü		
21.27			Report on its own internal review processes	ü		
21.28-21.30			Additional information on further inputs to its internal reviews	ü		
21.31			Initial report called for by paragraph 21.31	ü		

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 of processes, product and service conformity, user satisfaction and the results of internal 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 operational governance structures, e.g. the EOC and the MAC.

~~An annual~~A ~~-~~quality review is carried out every ~~year~~ quarter to assess the efficiency and effectiveness of the QMS as well as the progress of all continual improvement actions. The ~~annual quarterly quality review is chaired by the~~ President~~, who~~ sets the ~~new~~ yearly quality objectives, approves quality action plans and ensures that the QMS and the Quality Policy are fit for purpose in view 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 under the quality action plan and achievement of the quality objectives, and to review the actions planned 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 emphasise the importance of quality as an indicator of the degree to which product characteristics fulfil the Treaty and regulatory requirements. Quality data is presented to all operational management teams in the form of "integrated quality reports" and then communicated to staff.

(b) Internal communiqués from top management are published internally on a regular basis on QMS implementation, the yearly quality objectives and results from the previous year. Further means of communication are used to address quality matters at all levels of the organisation (e.g. Quality webpage, posters, flyers, videos, workshops, training/awareness sessions, e-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 reviews the effectiveness, suitability and adequacy of the QMS. This includes determining the necessary resources and reviewing quality objectives. Quality objectives are communicated to staff via the intranet, at meetings as well as within the regular performance management framework; 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 ~~annually~~ quarterly reviews the effectiveness, suitability and adequacy of the QMS as indicated in the annual quality report. This review incorporates data relating to the monitoring and measurement of PCT product and service conformity and of the PCT search and examination process. The results of the top management review are recorded.

21.10 Indicate whether top management of the Authority promote practices to ensure that risks and opportunities that can affect its QMS and the conformity of international search and examination are addressed.

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 minimise 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 corporate risk management (CRM) framework based on the risk management guidelines of ISO 31000 and the Committee of Sponsoring Organizations and the Treadway Commission (COSO). PD CGS oversees the overall risk management process for the organisation, evaluates its application and suggests improvements.

The President is responsible for the overall risk management and ~~. He:~~

- a~~A~~ssigns risk owners;~~,~~
- d~~D~~efines what risks and what level of risks are acceptable for the EPO; and ~~,~~
- r~~R~~eviews ~~reviews~~ risks quarterly and follows ~~-~~up on actions taken to reduce the risk exposures to acceptable levels.

The responsibility for risk management cascades down following the EPO management structure. At each level risks are managed in accordance with the entrusted areas of responsibilities.

Risks, opportunities and issues identified are assessed to understand their impact on the EPO, departments and the ability to meet the objectives, needs and expectations of interested parties.

~~The EPO's risk management framework is based on a federated approach, which means that each department manages its own risks, but all risks are centrally tracked in a single corporate risk register that is accessible to all EPO departments and used to report and manage risks and opportunities. The single corporate risk register ensures awareness and transparency and~~

provides an opportunity for different departments to collaborate when mitigating the same or similar risks or to exploit opportunities together.

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

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

Risk management is a key management responsibility. Identification, risk mitigation and follow-up is their responsibility.- and especially The identification of risks is integral to the day-to-day work of every EPO staff member.

As of Autumn 2021, tThe newly established ISO practitioners network will supports local management teams in daily ISO management systems, including risk management. At the heart of the EPO risk management framework is a network of risk practitioners operating throughout all DGs and guided by PD CGS.

RiskISO practitioners will use their expertise to facilitate the risk management process for management. They will help to identify risks, assess them, record them in the EPO risk register and follow up with response plansmitigation actions.

Risks, opportunities and issues identified are assessed to understand their impact on the EPO, departments and the ability to meet the objectives, needs and expectations of interested parties.

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

3. RESOURCES

21.15 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 based on a medium-term business plan (MTBP) which is reviewed annually depending on operational needs. Goals in timeliness of delivery of products and services are translated into the needed level of resourcing. The President, in accordance with the advice provided by the MAC, approves the MTBP and reports on it to the Administrative Council.

Examiners and formalities officers are recruited in accordance with the skills requirements specified in the relevant job descriptions. They also receive on-the-job training (see point (vi) below).

Examiners and formalities officers must be able to work in all three official EPO languages. To that end, the EPO 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 workstation consisting of a computer with access to a platform hosting all relevant software applications for classification,

search and examination, as well as with access to the intranet and internet. The applications are maintained by the Business Information Technology unit. All examiners and formalities officers are able to telework. The teleworking scheme provides necessary hardware and software tools allowing equal access to all platforms mentioned above via a standard internet connection.

(iv) Every examiner has access to internal and external databases in accordance with the requirement of Rule 34 PCT. The documentation is stored solely on electronic media. The maintenance and quality of the stored data is ensured by the Information Processing 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 are 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 organised and documented by DG 4's Directorate Talent Management.

The initial training for new examiners is six-weeks of ~~classroom~~ training, initially foreseen as classroom training.~~.~~ In 2021, due to the pandemic situation, all trainings ~~were~~ was ~~exceptionally~~ held on-line. The EPO will review the training modalities, once the pandemic measures are no longer present.

Within the first two years of employment examiners receive ~~a total of 59 days of~~dedicated ~~classroom~~ training and are assisted by a tutor in their daily work. Experienced examiners receive further courses on specific procedural aspects of the patent granting procedure.

Formalities officers receive an initial two to four weeks of ~~classroom~~ training, depending on the procedures they are recruited for, and are supported by a coach whenever needed. Afterwards they receive training on additional procedures either on the job or in a specific 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.

DG1 management is responsible for ~~the~~ production and workforce planning, each at their level. They manage the quality of their output. All DG1 resource requirements come together in the medium-term business plan (MTBP) which is reviewed annually depending on operational needs.

Principal Directorate Business Analysis and ~~Planning~~ Performance ~~under the responsibility of the Vice-President DG 1 (Patent Granting Process)~~ is in charge ~~for~~ of providing estimates of

required examiners and formalities officers and helping to monitor performance against objectives.

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

4. MANAGEMENT OF ADMINISTRATIVE WORKLOAD

21.16 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 managers have access to a number of software applications which allow them to monitor and manage priorities, timeliness, backlog and requests for search and examination. Principal Directorate Business Analysis and Planning Performance within PD VP 1 Office provides monthly reports with operational statistics to the DG 1 management team.

5. QUALITY ASSURANCE

21.17 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.

PD Quality, Business and User Services and Practice Harmonisation proposes quality objectives according to the quality strategy. These objectives are endorsed by top management.

Quality-related results including timeliness and product quality are presented to reviewed regularly by operational managementoperational management teams by the quality lead directors (one per sector), who report to the DG 1 Quality Committee. . TheseRegular reports focussing on key quality issues and presenting the most relevant quality aspects are regularly discussed by the management. The reports arewhich 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.

Since 2014, the Patent Grant Process has an operational quality control mechanism in place that is continuously further developed. The three--member examination division is a further safeguard to ensure that in DG 1 is carried out according to the CASE procedure (Conformity Assurance for Search and Examination). According to this procedure, a record is kept of any nonconformityies are detected and , the re-verification step and the corrective actions are taken before releasing the product.

The methodology applied for carrying out formalities officers' operational quality control was improved in 2014 to better suit business needs and is now fully integrated into the EPO's QMS (OQC-FO).

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

Directorate Quality Audit carries out product audits, in particular on classification, grants and search products as well as opposition, refusals and formalities products. Since October 2020 the auditors contact the examining divisions in case of disagreement for a grant or a search. This audit dialogue is further complemented by in-depth meetings with operational experts to identify particular recommendations from the noncompliant cases. A rotation cycle of 3 years for auditors is in place since 2020.

6. COMMUNICATION

Inter-Authority communication:

21.18 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)

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

(a) helping identify and disseminate best practice among Authorities;

(b) fostering continual improvement; and

(c) providing for effective communication with other Authorities to allow for prompt feedback from them so that potential systemic issues can be evaluated and addressed.

The President: email to president@epo.org

PD CGS and PD ~~QBUS~~QPH: email to quality@epo.org

Communication and guidance to users:

21.20 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) Principal Directorate Customer Journey and Key Account ~~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 may be involved in the complaint handling procedure (e.g. for providing feedback and if required

for taking suitable corrective and/or preventive actions). Since 1 January 2014, the EPO website has a web form for submitting complaints online. Since ~~November~~November 2021 the web form ~~offers a choice for users if they wish~~also offers users the option to provide feedback.

An analysis of user feedback received in the form of complaints, feedback and within the framework of user satisfaction surveys is provided in the annual quality report and the intermediate quality report, both of which are used by top management for the review of the QMS. Quality issues requiring corrective, preventive or improvement actions are recorded 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, together 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~~programme was ~~is being~~ redesigned to follow~~ing user consultation.~~ a user-centric approach derived from internal and external user consultations. It covers the entire end-to-end user journey with the patent granting process including support services and is conducted biennially. The 2020-2021 cycle was concluded in October 2021.

(iii) A guide for applicants is available on the EPO website at epo.org/applying.html.

(iv) The EPO approach to quality is published on the website at epo.org/about-us/services-and-activities/quality/policy.html. A link to publicly available quality indicators can also be found on the website.

21.21 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.

A number of EPO departments are regularly represented 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 in Principal Directorate Quality and Practice Harmonisation (see 21.0~~1~~4, above).

7. DOCUMENTATION

21.22 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)

21.23 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 Quality webpage.

The document control measures taken comply with the requirements of ISO 9001:2015.

21.24 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 organisational 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.

21.25 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~~ quarterly quality review and intermediate quality review ~~as well as QB~~ meeting minutes (including outcomes) are kept in a database administered by ~~the~~ Directorate ~~Operational~~ Quality ~~and Risk~~ Management~~QB~~.

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

(iv) QMS certification according to ISO 9001:2015 for the patent process.

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

(vi) (vii) All documentation relating to the search and examination processes carried out on an application is collated in the electronic file and is stored centrally.

(viii) Records of QMS audits are kept in a central audit database administered by PD Internal Audit and ~~Oversight~~Professional Standards.

(ix) The EPO has two mechanisms for detecting nonconforming products in search and examination during the PCT phase; i.e. checks by the director and checks by a different examiner. Nonconformities detected and corrective action taken are recorded in a dedicated database and discussed with the original examiner.

(x) (xi) Records of recurrent nonconformities detected 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 a process owner when a given KPI falls below a threshold value. This allows the process owner to take suitable preventive action to ensure that the objectives set for the process are met. Records of preventive action are kept in a dedicated database.

(xii) Yes, for details see section 8~~7~~ below.

8. SEARCH PROCESS DOCUMENTATION

21.26 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 records have been kept since 1 July 2010 and include 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

21.27 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.

21.28-21.30 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.

The first review according to Chapter 21.10 carried out in 2007 identified actions necessary to ensure 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 to assess the effectiveness of the QMS against organisational goals and quality objectives.

Since achieving ISO 9001 certification of its QMS, the EPO has 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

21.31 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 uses revision marks to track changes that have been made to the previous report dated ~~29 November 2019~~8 February 2021.

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