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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 (EPO) 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 enhancing this leading position through strong and effective dedication to quality at all levels.

The EPO's quality management system (QMS) has been certified to ISO 9001:2015 for the entire patent process since 2014.

In 2019, the EPO adopted its Strategic Plan 2023 (SP2023), which 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 was to enhance process efficiency. The EPO intended to extend the scope of its ISO 9001 certification to all areas of the organisation as well as bring all management systems together and pursue other ISO certifications, in particular ISO 27001.

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

In 2022, the EPO successfully extended the scope of the QMS to all areas of the organisation and obtained initial certification of its information security management system under ISO 27001:2013 (2017).

SinceIn 2023, Directorate Corporate Performance, Risk and Compliance (D CPRC) was created in Directorate-General Corporate Services (DG 4) is responsiblewith the mandate of for maintaining the QMS and all EPO management systems in the integrated management framework as well as overseeing and reporting on corporate level risk management and business continuity activities.

In 2024, Tthe EPO successfully passed the surveillance audits related toagain achieved certification under the ISO standards for management systems pertaining to quality (ISO 9001), and occupational health and safety (ISO 45001) and successfully passed the first surveillance audit relating to information security (ISO 27001). For the latter, the conformity was assessed in relation to the version 2022 of the standard.

The audits also formally recognised that the EPO integrated management system (IMS) relies on a holistic management culture based on continual improvement.

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 specified by top management.

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

(a) In line with the integrated management strategy, the elements of the EPO's 2013 Quality Policy that are wholly applicable have been integrated into the EPO's Corporate Policy. The EPO's Corporate Policy is communicated internally and published at epo.org/about-us/office/mission.html.

Since 1 October 2022, the EPO's Corporate Policy has been complemented by the new Patent Quality Charter reflecting the EPO's dynamic approach in keeping our products closely aligned with stakeholders' demands and expectations. The Patent Quality Charter is accessible at epo.org/about-us/services-and-activities/quality/policy.html.

(b) The President has overall responsibility for the QMS and establishes the Corporate Policy and quality objectives to support the QMS. The President promotes the Corporate Policy, the Patent Quality Charter and quality goals within the organisation and vis-à-vis 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) assists the President in overseeing the effectiveness of the EPO and proposing initiatives and policy changes that can potentially impact the EPO's activities and reputation (epo.org/about-us/leadership-and-management/management-committee.html).

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 of co-ordinating the maintenance and improvement of the QMS at all levels of the organisation is assigned to Directorate Corporate Performance, Risk and Compliance.

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

The EPO's integrated management governance structure includes the President, who has overall responsibility for the QMS, with the MAC's support. ~~Operational elements of the management systems have been integrated into the Executive Operations Committee (EOC) under the chairpersonship of Vice-President DG 1 (Patent Granting Process or PGP), while including all internal stakeholders. This also includes recommending and monitoring the implementation of quality improvement measures~~.

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 of their processes
- establishing and maintaining the related QMS documentation
- providing feedback to the appropriate MAC members and relevant executive management committees.

Directorate Corporate Performance, Risk and Compliance (D CPRC) is dedicated to maintaining the EPO's QMS and designing, implementing and maintaining the integrated management framework, bringing together all the EPO's management systems. It is further responsible for conducting internal ISO audits to assess compliance with the requirements of all applicable ISO standards, in particular ISO 9001 for the QMS. D CPRC maintains a centralised oversight of all the EPO's corporate quality aspects and the EPO's Corporate Policy.

Principal Directorate Quality and Practice Harmonisation (PD QPH) maintains the ISO 9001:2015 QMS for the patent granting process, promotes harmonisation and consistent practices and supports continual improvement of operational quality. PD QPH has the co-ordinating role in maintaining the Patent Quality Charter.

Principal Directorate Customer Journey and Key Account Management brings together services to support customers in their journey through the patent granting process. Moreover, it provides an insight into the needs of European patent system users so that the EPO can serve them better.

Directorate Quality Audit, within Principal Directorate Internal Audit and Professional Standards, is responsible for carrying out our product audits. Since October 2021, the search audit has been extended to include written opinions.

Senior and line managers ensure that quality objectives, the Corporate Policy and the Patent Quality Charter are communicated to staff. When applicable, they translate top-level quality objectives into local quality objectives.

Staff deliver products and services to users by following the applicable statutory and regulatory requirements and work instructions. They consult QMS processes and other relevant documents where necessary. They have the authority and responsibility to initiate action to prevent the occurrence of product or process non-conformity and to identify and report any quality issue.

(c) The graphical representation of the current organisational structure is available at epo.org/en/about-us/at-a-glance.

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 search and examination (S&E) complies with PCT Guidelines	✓		
		(c)	an objective and transparent way	✓		
		(d)	using input incl. information according to paragraph 21.29	✓		
		(e)	recording the results	✓		
21.10			Risk and opportunities are addressed that can affect the QMS and the conformity of search and examination	✓		
21.13			Arrangements for establishing risk-based practices to	✓		
	(i)	(a)	understand issues that affect its ability to achieve intended results of the QMS	✓		
		(b)	understand the needs and expectations of interested parties	✓		
	(ii)		identify risks and opportunities related to the performance of the QMS as a basis for planning	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
	(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	✓		
21.16	(i)		Control mechanisms to ensure timely issue of S&E reports	✓		
	(ii)		Control mechanisms regarding fluctuations in demand and backlog	✓		
21.17	(i)		Internal quality assurance system for self-assessment	✓		
		(a)	for compliance with S&E Guidelines	✓		
		(b)	for channeling feedback to staff	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
	(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	✓		
	(iii)		Organizational structure and responsibilities	✓		
	(iv)		Documented processes carried out in the Authority	✓		
	(v)		Resources available to carry out processes and implementing the procedures	✓		
	(vi)		Description of the interaction between the processes and the procedures of the QMS.	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
21.25	(i)		Records of 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)		Records of evidence of conformity of processes, resulting products and services in terms of quality standards	✓		
	(v)		Records of results of reviews of requirements relating to products	✓		
	(vi)		Records of the S&E process carried out on each application	✓		
	(vii)		Records of data allowing individual work to be tracked	✓		
	(viii)		Records 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 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.

A quality review is carried out every month to assess the efficiency and effectiveness of the QMS as well as the progress of all continual improvement actions. The President sets the yearly quality objectives, approves quality action plans and ensures that the QMS and the Corporate Policy are fit for purpose in view of the organisation and the requirements of the relevant interested parties.

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) Activity reports emphasise the importance of quality as an indicator of the degree to which product characteristics fulfil the Treaty and regulatory requirements. Quality data are shared regularly with operational management teams via the Quality Committee and then communicated to staff. The set quality objectives and the yearly quality action plan are regularly made available by the EPO and shared with the community of users.

(b) Internal communiqués from top management on QMS implementation are published internally on a regular basis, along with 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. webpage, posters, flyers, videos, workshops, training/awareness sessions and 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 by the relevant staff at 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. In 2024 a new quality dashboard was also set up and made available both to internal staff and to external users

21.09 Indicate whether top management or delegated officers of the Authority perform an internal review of the QMS in accordance with paragraphs 21.27-21.30:

(a) at least once per year (cf. paragraph 21.27);

(b) in accordance with the minimum scope of such reviews as set out in Section 9, namely:

to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.27, 21.29(i));

to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.27, 21.29(i));

(c) in an objective and transparent way (cf. paragraph 21.27);

(d) using input including information according to paragraphs 21.29 (ii)-(vi);

(e) recording the results (cf. paragraph 21.30).

Each quarter, the EPO's top management reviews the effectiveness, suitability and adequacy of the QMS. This review incorporates data relating to the monitoring and measurement of PCT product and service conformity as well as 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 minimize negative effects, and to make use of opportunities as they arise.

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

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

21.13 Arrangements for establishing risk-based practices

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

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

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

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

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

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

(v) continuously update risks and opportunities.

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

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

In 2020, the EPO started to implement a corporate risk management framework based on the risk management guidelines of the Committee of Sponsoring Organizations and the Treadway

Commission. D CPRC 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:

- assigns risk owners
- defines what risks and what level of risks are acceptable for the EPO
- reviews risks quarterly and follows up on actions taken to reduce 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 entrusted areas of responsibilities.

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

D CPRC 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. It manages corporate risks and produces reports on risk management. It also supports local risk management teams and audit processes and procedures related to risk management.

D CPRC reports regularly to the EPO's top management on the main risks and opportunities requiring attention. Risk reports are also shared with Principal Directorate Internal Audit and Professional Standards for the purpose of internal audit planning.

Risk management is a key management responsibility and includes identification, risk mitigation and follow-up. The identification of risks is integral to the day-to-day work of every staff member of the EPO. As of autumn 2021, the newly established ISO practitioners' network has been supporting local management teams in daily ISO management systems, including risk management.

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~~Workforce planning is based on a medium-term business plan (MTBP) which is reviewed annually in line with operational needs with due consideration for financial and strategic orientations. Goals on efficiency and ~~the~~ timeliness of delivery of products and services are translated into the required level of resourc~~es~~~~ing~~. The President, in accordance with 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 skill requirements specified in 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 languages of the EPO. To that end, the EPO offers suitable courses on a regular basis.

(ii) Staffing levels are determined on the basis of 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 are 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 access to the intranet and internet. The applications are maintained by the Business Information Technology (BIT) unit. All examiners and formalities officers have the option of teleworking. The teleworking scheme provides the necessary hardware and software tools allowing equal access to all platforms mentioned above via a secure internet connection.

(iv) Every examiner has access to internal and external databases comprising the minimum documentation to be consulted under Rule 34 PCT. The documentation examiners work with is stored solely on electronic media. The maintenance and quality of the stored data is ensured by BIT.

(v) The relevant legal texts and instructions (e.g. PCT, EPC, Guidelines and Internal Instructions) are accessible to all staff via the EPO website and/or internally via the Single Legal Source (SLS) database. Staff are kept up to date on the latest amendments by means of dedicated procedural 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 Directorate Talent Management in Principal Directorate People ~~in Principal Directorate People (PD42)~~ in Directorate-General Corporate Services (DG 4).

Initial training for new examiners is provided in ~~six~~ seven classroom courses during the first two years of employment, alongside continuous support by one or more certified coaches from the same or closely related technical field. ~~After a period of online delivery of the classroom courses due to the pandemic, i~~Initial training courses are ~~have resumed to be~~ largely on site, with a few exceptions where the online setting provided some benefits. Experienced examiners receive further courses on specific procedural aspects of the patent granting procedure, for example, when they take up a new role such as chair in examination, classifier or the different members of opposition division. Ad hoc training is also organised for the roll out of new tools or other strategic needs.

~~Formalities officers initially receive two-four weeks of training, depending on the procedures they are recruited for, and are supported by a coach whenever needed. They subsequently receive training on additional procedures, either on the job or in a specific classroom training module, followed by coaching assistance at the discretion of their line manager.~~ For formalities officers, tailored learning paths to accommodate staff with varying levels of prior knowledge were provided. Refreshers were offered to experienced formalities. An internal EPAC study group for EPO staff, particularly formalities officers, support was scaled up in 2024.

Examiners and formality officers are also offered language courses for the three official languages from the EPO. Both examiners and formality officers can attend a wide range or personal effectiveness courses. There is also extensive management training offered for team managers and directors.

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.

Management in Directorate-General Patent Granting Process (DG 1) is responsible for establishing production and capacity plans involving each manager at their respective hierarchical level. They are also responsible for the quality of output in their units.

Operational assumptions for the next five years (e.g. examiner and formalities officer capacity, production, productivity, patent publications, incoming workload and stocks) are included in the Medium-Term Business Plan, which is reviewed every year to reflect the latest strategic orientations of the EPO.

Principal Directorate Business Planning and Performance ~~—~~ under the responsibility of the Vice-President DG 1 – supports the monitoring of performance against objectives.

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 several software applications which allow them to monitor and manage priorities, timeliness, backlog and requests for search and examination. Principal Directorate Business Planning and Performance provides monthly reports with operational statistics to the DG 1 management team.

5. QUALITY ASSURANCE

21.17 In accordance with the Guidelines, the following are required quality assurance measures for timely issue of search and examination reports of a high quality. Indicate how the following are implemented, including the use of any checklists to verify reports before their issue or for monitoring the quality as part of a post-issue review process:

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

for compliance with these Search and Examination Guidelines;

for channeling feedback to staff.

(ii) A system of measurement and collection of data and reporting. Show how the Authority uses the system to ensure the continuous improvement of the established processes.

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

Principal Directorate Quality and Practice Harmonisation proposes quality objectives for the patent grant process, in line with the quality strategy. These objectives are endorsed by top management.

Quality-related results including timeliness and product quality are reviewed regularly by operational management. Reports focusing on key quality issues and presenting the most relevant quality aspects are regularly discussed by the management. The reports are derived from different quality-related data sources, e.g. user satisfaction surveys, operational quality control, quality indicators, complaints and internal audits.

Identification of 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 granting process has an operational quality control mechanism in place that is continuously developed. The three-member division is a further safeguard to ensure that non-conformities are detected and corrective actions are taken before the product is released.

The methodology applied for carrying out formalities officers' operational quality control was improved in 2018 to better suit business needs and is now fully integrated into the EPO's QMS (FO-OQC).

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

Directorate Quality Audit carries out product audits on classification, grants and search products as well as opposition, refusals and formalities products. Since October 2020, the quality auditors have been contacting the divisions in case of disagreement on a grant or search. This audit dialogue is further complemented by in-depth meetings with operational experts to identify specific recommendations from non-compliant cases. A rotation cycle for auditors has been 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 21.18)

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 president@epo.org

PD QPH: email quality@epo.org

Ombuds Office: email ombuds@epo.org

Support: support@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.

Indicate where and how the Authority makes its quality objectives publicly available for the users.

(i) Principal Directorate Customer Journey and Key Account Management is responsible for the administration and management of enquiries, external complaints and feedback to the EPO. Depending on the nature of the enquiry, complaint or feedback, other departments may be involved in the handling procedure (e.g. to provide feedback and, if required, to take suitable corrective and/or preventive actions). Since 1 January 2014, the EPO website has a form for submitting complaints online. Since November 2021, the form also offers users the option to provide feedback.

An analysis of user feedback received in the form of complaints, feedback and responses to user satisfaction surveys is reported internally to ~~the EOC~~top management on a monthly basis. Detailed results are made available in the Quality Report which is published also externally after the Administrative Council of June. The results of the user feedback are used as input to the annual quality action plans of the following year. Quality issues requiring corrective, preventive

or improvement actions are recorded in a quality improvement database as Quality Initiatives (QIs).

The EPO has established and maintains a documented corrective action procedure to eliminate the causes of non-conformity and prevent recurrence, together with a list of preventive actions and risk management to eliminate the causes of potential non-conformities. Corrective and preventive actions taken are proportionate 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 QIs database.

(ii) The user satisfaction survey (USS) programme has been ~~was~~ redesigned to incorporate a user-centric approach derived from internal and external user consultations. It covers the entire end-to-end user journey of the patent granting process including support services and is conducted biennially. The most recent cycle 2022/2023, contained 7 000 user responses and was finalized and presented to the EPO Administrative Council in June 2023 and published immediately thereafter on the EPO website (https://www.epo.org/en/news-events/news/epo-publishes-results-latest-user-satisfaction-survey). On 1 September 2024, the third end-to-end USS was launched and will be completed during the first half of 2025.

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

(iv) The EPO approach to quality is published at epo.org/about-us/services-and-activities/quality.html. In 2024 a new quality dashboard was made available to the public together with the yearly quality action plan~~, along with a link to publicly available quality indicators~~.

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 the EPO's departments are regularly represented at WIPO meetings and there are regular exchanges with WIPO on operational and IT matters. Feedback from WIPO is addressed by the relevant departments; in particular, feedback related to product quality matters is addressed by Directorate Quality Management in Principal Directorate Quality and Practice Harmonisation (see 21.04, 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 by documenting the procedures and processes affecting the quality of work as a reference for staff and management at the Authority (see paragraph 21.23).

(Note: This point is informative. No response is required by the template to paragraph 21.22)

21.23 The material that makes up the reference for staff and management at the Authority serves to document the procedures and processes affecting the quality of work, such as classification, search, examination and related administrative work. In particular, the reference indicates where to find instructions on the procedures to be followed.

For the purposes of this report indicate:

(a) the documents making up the reference that have been prepared and distributed;

(b) the media on which they are supported (e.g. Internal Publication, Internet, Intranet); and

(c) document control measures taken e.g. version numbering, access to latest version.

All process descriptions and related procedures are available in the Integrated Management portal and document repository. Operational/legal instructions and guidelines related to patent quality are accessible to examiners and formalities officers through the SLS portal.

The documents are checked to ensure that they meet the requirements of ISO 9001 and ISO 27001.

21.24 Indicate whether the material making up the reference of quality procedures and processes include the following:

(i) the quality policy of the Authority including a clear statement of commitment to the QMS from top management;

(ii) the scope of the QMS, including details of and justification for any exclusions;

(iii) the organizational structure of the Authority and the responsibilities of each of its departments;

(iv) the documented processes carried out in the Authority such as receipt of incoming applications, classification, distribution, search, examination, publication and support processes, and procedures established for the QMS, or references to them;

(v) the resources available for carrying out the processes and implementing the procedures; and

(vi) a description of the interaction between the processes and the procedures of the QMS.

These documents are all accessible through the Integrated Management portal.

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 8.

(i) (ii) Relevant documentation and locations are defined in the Integrated Management System (IMS) documentation. The regular quality review meeting minutes (including outcomes) are kept in a database administered by Directorate Quality Management.

(iii) Records of staff competencies, development and training received are kept in a database administered by Principal Directorate People. Staff have access to these records via MYFIPS portal.

(iv) QMS certification according to ISO 9001:2015 for the patent process. The ISO certificate achieved in ~~2023~~ 2024 is available from the Transparency Portal (epo.org/en/about-us/transparency-portal). The Transparency Portal provides easy access to information on the

EPO's operations and sustainability efforts, organised in line with the Global Reporting Initiative (GRI) standards.

(v) Records are maintained where applicable. The results of reviews are stored in internal databases.

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

(viii) Records of ISO audits are kept in a central audit database administered by D CPRC.

(ix) The EPO has different mechanisms for detecting non-conforming products in search and examination during the PCT phase, i.e. checks by the line manager and checks by a different examiner. The non-conformities detected and corrective actions taken are recorded in a dedicated database and discussed with the original examiner.

(x) (xi) Records of recurrent non-conformities detected and 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 for process owners that monitors 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) For details on the search process documentation, see section 8 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 document 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 ISO audits under all relevant ISO standards, including ISO 9001:2015.

Since achieving ISO 9001 certification of its QMS, the EPO has committed to carrying out an annual internal review, which is also 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 21.31(a), and annual reports in accordance with paragraph 21.31(b). 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 present report uses revision marks to track changes that have been made to the previous report dated ~~15 February 2023~~12 April 2024.

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