

ORIGINAL: ENGLISH

DATE: 21 2815 JANUARY FEBRJANUARY 2022 20234

Patent Cooperation Treaty (PCT)

Common Quality Framework for International Search and Preliminary Examination

INITIAL REPORT ON QUALITY MANAGEMENT SYSTEMS

prepared by THE EGYPTIAN 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 Egyptian Patent Office (EGPO) was established in 1951. Since 1971, EGPO has been operating under the Academy of Scientific Research and Technology (ASRT). EGPO provides professional, efficient and high standard substantive and formality examination procedures for patent applications.

Since 2013, EGPO has become a PCT International Searching and Preliminary Examining Authority (ISA). EGPO is the first ISA in Africa and the Arab region. It and is currently the only ISA that issues ISR and WOISA in both the Arabic and English languages.

The mission of EGPO is not only limited to conducting search and examination for patent applications and granting patents. EGPO has a crucial role in the advancement of science and technology in Egypt by encouraging the efficient use of the protection and information functions of the patent system. EGPO endeavors to contribute to the socioeconomic development of Egypt by supporting R&D activities and fostering innovation. Therefore, it provides information and expertise on intellectual property (IP) and patents through various awareness raising and training activities.

EGPO is committed to offering high quality patent system products and services and therefore, it keeps on adopting high quality procedures and practices. During 20202022, a number of noticeable developments and improvements were introduced.

In September 2022, EGPO has obtained its ISO 9001:2015 Certificate on Quality Management Systems. EGPO top management has been seeing this as a very important objective to achieve in 2022 as the importance and complexity of the role EGPO plays on the national and international levels increase. The ISO 9001:2015 Certificate- has been renewed in September 2023.

Starting January 2022, EGPO fully launched its e-filing and e-services system (EGPO–SES) and since then all applications and services requested are received and processed electronically by EGPO via the system.

<u>EGPO has finalized setting the e-filling and e-services system (EGPO-SES).</u> <u>EGPO-SES consists of two portals:</u>

- E-filling portal that provides many services such as filling new applications, following up actions and modifications amendments, e-payment and notifications, and a number of offered services, for example, translation, translation check, issuing a certified copy...etc.
- Patent Search portal that serves two different type of users:
 - Public users: the portal provides public search with advanced features that enable them to search EGPO published patents.
 - EGPO Examiners: the portal enables examiners to search all EGPO patent applications.

 Full-text search is made available. Patent examiners can leave saved notes on their search and save memos on all the search process they have conducted.

EGPO has trained patent agents, and representatives of focal points and Technology and Innovation Support Centers (TISCs) effices in universities and research institutions on using the EGPO-SES. A number of webinars on the e-filing system and procedures were conducted also targeting the general public and individual users.

EGPO is keen to provide information to users of the patent system about the various steps of the patent procedures. The guide for patent applicants – available on EGPO website – has been revised and updated. It provides guidance on all the steps required to file applications and follow the procedures from filing until a final decision is reached, as well as the conditions and requirements that have to be met under the Egyptian IP Law. EGPO has issued a guide on examining patent applications in the biotechnology field which was made available on the website. Also, a comprehensive user guide is available on the EGPO-SES system with all details on the steps of creating an account, performing e-filing, and e-payment, and requesting e-services. Another user guide for performing patent search was developed and is also made available on the search system of EGPO-SES.

During 2023, EGPO started a pilot to send notifications to patent applicants via email system reflecting decisions or actions taken on EGPO SES. In addition, a weekly publication of issued office actions is made available on EGPO website to serve as a basis for calculating relevant legal time limits.

Efforts are underway to enhance the accuracy and efficiency of EGPO's internal database and its patent search system through converting PDF documents to searchable text format through OCR programs and data validation of the applications bibliographic data.

Also, in September 2022, EGPO had successfully completed its Twinning Project with the EU: "Supporting and Upgrading the Institutional, Technical and Raising Awareness Capabilities of the Egyptian Patent Office" with very fruitful results in particular in relation to enhancing the EGPO QMS, staff capacity, and support services to users especially SMEs, and academic and research institutions.

Most importantly, September 2022 witnessed a significant national event which was the launch of Egypt's National Intellectual Property Strategy. A Specialized National Committee has been established upon a Presidential Directive executed by a Prime Minister's Decision to develop a national IP strategy. The Committee that has worked for about two years was headed by a representative of the Council of Cabinet Legal Advisers, and its membership included all ministries and national authorities concerned with the management and protection of Intellectual Property Rights in addition to experts. EGPO was represented in the Committee and positively contributed to the work performed by the Committee in general and also by many of the working groups formed to perform specific tasks. The launched IP strategy has 4 strategic goals: Governance of the Institutional Structure of IP, Configuring the legislative Environment for IP, Optimizing the Economic Return of IP in Achieving the SDGs, and Raising Awareness of the Egyptian Society on IP. EGPO will be involved in implementing various projects and initiatives under the strategic goals and the sub-objectives of the National IP Strategy.

In August 2023, Law 163 year 2023 on the establishment of the Egyptian Intellectual Property Authority (EIPA) was enacted. As per the law, and within the framework of the first Strategic Goal of the National IP Strategy, all IP Offices in Egypt including EGPO will be operating under EIPA. A transitional period is currently running until all IP Offices are administratively and physically joined under EIPA.

The e-PCT system is utilized on a wider basis by EGPO technical examiners and the personnel of the PCT Department SA Unit in Technical Examination Department. Technical Examiners are now processing International Applications, preparing and submitting international reports through e-PCT. Applicants are able to create accounts on e-PCT to file and follow up their PCT applications through their respective accounts. The Information Technology Department personnel along with the PCT Receiving Office personnel provide support services to PCT applicants on creating e-PCT accounts and following their applications through e-PCT.

Several Most of the examiners have keep developing their knowledge and skills through attendinged various training activities which were organized in cooperation with WIPO and other Patent Offices. Among the 36 IP trainers in the National IP Academy there are 16 examiners from EGPO; 14 technical examiners and 2 legal examiners. Two twin training courses on patent search examination, targeting patent examiners in the Arab and African Regions are annually in particular in the pharmaceutical field, were organized in cooperation with WIPO Academy the South Centre and the Third World network, and delivered by a group of the EGPO pharmaceutical examiners and trainers. In addition, a sub-regional workshop on PCT Receiving Office Functions and the

PCT System for IP Office users and a national workshop on IP Offices support services to SMEs were conducted in collaboration with WIPO.

New features on the IPAS system were activated allowing for more efficient monitoring and follow up of workload.

ECPO has finalized setting the e-filling and e-services system (ECPO-SES). ECPO-SES consists of two portals:

- E filling portal that provides many services such as filling new applications, following up actions and modifications, e-payment and notifications, and a number of offered services, for example, translation, translation check, issuing a certified copy...etc.
- Patent Search portal that serves two different type of users:
 - Public users: the portal provides public search with advanced features that enable them to search EGPO published patents.
 - EGPO Examiners: the portal enables examiners to search all EGPO patent applications. Full text search is made available. Patent examiners can leave saved notes on their search and save memos on all the search process they have conducted.

EGPO has trained patent agents, and representatives of focal points and Technology and Innovation Support Centers (TISCs) offices on using the EGPO-SES.

Support services are made available (in-person and through email, virtual meetings and phone calls) for troubleshooting technical issues and offering help for all users to overcome any obstacles they might face upon using the e-services.

EGPO has revised the main clauses in the MOUs with EGPO focal points and some of them were updated. The updates were taken into consideration in the recently signed MOUs.

EGPO recognizes the importance of Quality Management System (QMS) to ensure that all patent processing steps are completed in a timely and high quality manner. EGPO aims to maintain and improve its QMS as implemented for the PCT application processing according to Chapter 21 of the PCT International Search and Preliminary Examination Guidelines.

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)

EGPO quality policy has been established by top management. It is available internally to all EGPO staff and externally to all interested parties on EGPO's website.

The Quality Manual of EGPO (under development) will includes the quality policy, the bodies responsible for the QMS (including the Quality Department, the High Quality Committee (-HQC) and the Quality Review Committee (QRC)) and an organizational chart showing all the bodies and individuals responsible for the QMS for all the Departments of EGPO.

Our EGPO's key quality objectives for 2022/2023:

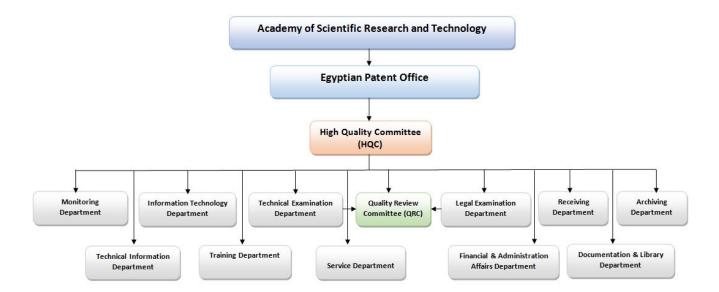
- Automatic mailing of 80% of the office actions to the applicants / users
- Implementing a Disaster Recovery Center
- Validation of Bibliographic Data on IPAS
- 1. Efficient delivery of the services and products, in a timely manner and in accordance with the Patent Cooperation Treaty and Regulations and the National Law.
- 2. Providing systems to meet the legitimate clients' needs and expectations.
- 3. Enhancing the staff skills through providing them with different training courses according to their needs.
- 4. Improving all the processes on basis of quality, cost and time.

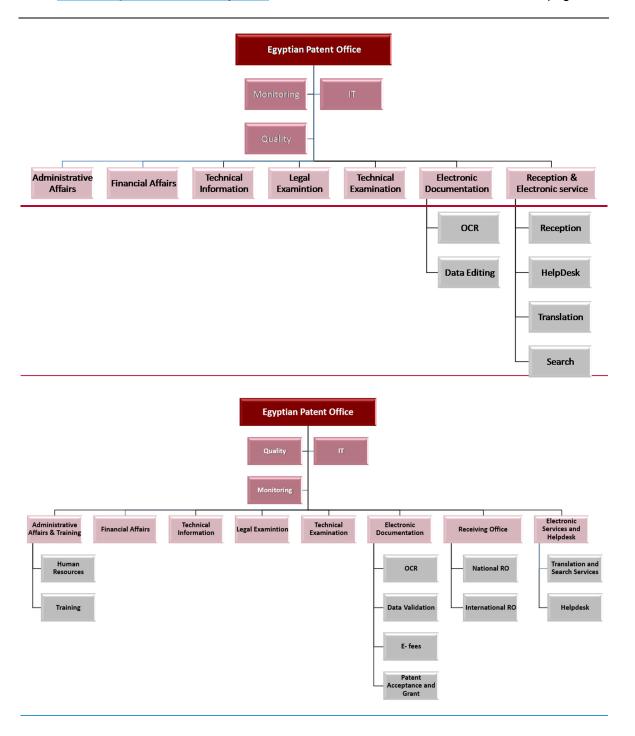
(b)

EGPO <u>has revised and updated</u> <u>does not have a special Department for QMS in its updated</u> administrative structure <u>, and now it includes a Quality Department responsible of its QMS but along with the already established and operating a High Quality Committee (HQC) and Quality Review Committee (QRC) were established and are considered a substitute for the QMS.</u>

- High Quality Committee (HQC): include members of at least the following Departments: (Technical Examination Department, Legal Examination Department, Information Technology Department, Quality Department, and Monitoring Department and Financial Affairs Department.
 - This committee follows up the workflow of the patent application ensuring that the work is performed according to quality standards in each department. The HQC identifies any deficiencies in the overall procedure, determines the reasons for them and proposes solutions.
 - The HQC prepares reports and submits them to the President of EGPO in order to put an action plan for implementing the recommendations of the committee.
 - Review the progress of comprehensive quality procedures and discuss quality-related issues.
 - Develop an action plan to implement quality management recommendations.
 - Receive and discuss the results of QRC reports.
 - Determine corrective actions based on the results of audit reports and QRC reports
- Quality Review Committee (QRC): is composed of legal examiners and technical examiners from different technological fields; chemistry, pharmacy, biotechnology, chemical engineering, electricity.... etc.

- The purpose of QRC is to verify, validate and monitor adherence to the Search and Examination quality standards particularly in light of the Search and Examination Guidelines and to provide feedback to the examiners— to improve the quality of the search and examination processes and the generated search and examination reports for patent applications in both the national phase and international phase.
- -Since January 2018, QRC was previously known as the Quality Sampling Review Committee (QSRC) as it was responsible for conducting revisions on random samples of accepted and rejected applications in the national phase and all international applications. In January 2018, this committee has becoame responsible of revising all accepted and refused patent applications in the national phase.





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).

[Sample table, to be amended as necessary]

Initial Report on Quality Management Systems by **The Egyptian Patent Office** 21-11 January 202428 January February 20222023

Chapte	oter 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 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	<u> </u>	≠	
21.13			Arrangements for establishing risk-based practices to	<u>√</u>	≠	
	(i)	(a)	understand issues that affect its ability to achieve intended results of the QMS	<u> </u>	≠	
		(b)	understand the needs and expectations of interested parties	<u>√</u>	←	
	(ii)		identify risks and opportunities related to the performance of the QMS as a basis for planning	<u>√</u>	≠	
	(iii)		plan and implement actions to address risks and opportunities	<u>√</u>	≠	
	(iv)		check the effectiveness of the actions taken	<u>√</u>	✓	
	(v)		continuously update risks and opportunities.	<u>√</u>	≠	
21.15			Assurance to monitor and adapt to actual workload	✓		
	(i)		Infrastructure in place to ensure that a quantity of staff	✓	1	

Chapte	er 21 ı	requi	ement Extent of compliance			е
				full	part	no
		(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	✓		
	(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	✓		

Initial Report on Quality Management Systems by **The Egyptian Patent Office** 21-11 January 202428 January February 20222023

Chapte	er 21	requi	rement	Extent of compliance		е
				full	part	no
		(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	<u>√</u>	←	
21.23		(a)	Material making up the reference of quality procedures and processes for staff and management has been prepared and distributed	<u>✓</u>	≠	
		(b)	Media available to support the reference material	<u>√</u>	←	
		(c)	Document control measures are taken	<u>√</u>	≠	
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.	√		
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	✓		

Chapte	Chapter 21 requirement		Extent of compliance		
			full	part	no
	(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	<u>√</u>	≠	
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.

⁽a) EGPO has established a Quality Department to be responsible of the management of its QMS along with the already established and operating HQC and a QRC.

page 12

High Quality Committee (HQC) and Quality Review Committee (QRC) are considered a substitute for QMS.

The High Quality Committee (HQC)Quality Department is responsible for monitoring and ensuring effectiveness of the QMS. ItThe HQC

HQC reviews the progress of the overall quality procedure and discusses quality related issues in a monthly periodical meetings with all the HQC members.

The purpose of QRC is to verify, validate and monitor adherence to the quality standards and to provide feedback to the examiners in both the national and international phase with regard to the generated search and examination reports.

The head of HQC holds a monthly meeting with the QRC members and the personnel of the ISA/IPEA Unit to discuss the quality reports for the national and international patent applications.

- In special situations, the head of HQC seeks legal advice from the legal consultants; Prof. Hossam Abdel Ghani El Saghir, Prof. Gamal Abdel Rahman, and Prof. Hassan Badrawy.

(b) Continual improvement progress

The head of HQC receives a monthly feedback from the Department Directors, HQC, and QRC and ISA/IPEA Unit members. From this feedback she revises whether the quality objectives are achieved and whether and what changes are needed.

- Conducting internal reviews at least once a year, in which the head of HQC meets with the Top Management, presents overall quality documentation and receives feedback and support.
- Taking the feedback from applicants into consideration.
- Ensuring efficient cooperation between the Technical Examination Department, PCT, HQC, QRC and IT Department.

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) and (b)

Meetings are held with the staff to explain the importance of complying to the quality standards and the conformity with the PCT treaty and regulatory requirements.

Regular Meetings are also held between the heads of HQC and QRC and the Director of the Technical Examination Department to discuss performance reports and emphasize the importance of adhering to quality standards of search and examination reports being the main products of the PCT procedure.

Internal workshops are conducted for the staff to discuss the PCT ISA and IPEA Procedures, any relevant updates on the process or documents, and to present case studies on special situations. The various departments have copies of PCT legal texts, guidelines and ISA/IPEA forms.

EGPO created an intranet for EGPO staff. It includes information and documentation on various items, such as relevant agreements, projects documents, and policies. This also includes details on the PCT Treaty, Regulation, Examination Guidelines, forms and other relevant documents in addition to information on the QMS and the necessity of complying to its standards.

page 13

The intranet is available for all EGPO staff after log in process. The intranet is continuously updated with documents to provide EGPO employees with all knowledge and information they need to know about the office.

<u>(b)</u>

For each technical section in the Technical Examination Department, the supervisor of the technical section and the Director of the Department revise and approve the search and examination reports prepared by the examiners. They make sure the generated reports conform to the quality standards. Identified issues in the reports are communicated to the respective examiners for correction. Depending on the nature and frequency of identified issues appropriate measures are taken to ensure they are not repeated.

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.

(a) - (c)

HQC holds a monthly meeting with top management to review the performance of its quality management system. During this meeting, quality objectives and the availability of appropriate resources are discussed and the necessary steps are taken. Quality objectives are periodically reviewed at the meetings of the HQC, in order to check their adequacy to the Quality Policy, and evaluate their achievement. The head of the HQC receives periodic feedback from the Department Directors, HQC members and QRC members on whether the quality objectives are achieved.

The QMS is annually reviewed by the Quality Department, HQC, together with the President of the EGPO. As part of the annual review, the availability of adequate and appropriate resources is assessed, and the degree of the achievement of the overall EGPO quality objectives and those of the various departments is reviewed and any obstacles or challenges are identified and analyzed for further action.

Quality objectives are periodically reviewed at the meetings of the HQC, in order to check their adequacy to the Quality Policy, and evaluate their achievement. The head of the HQC receives periodic feedback from the Department Directors, HQC members and QRC members on whether the quality objectives are achieved.

Once the QMS objectives are approved, the Director of each Department communicates them to the relevant personnel for their deployment and ensures they are fully understood.

DATE 27 February 2023 page 14

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).

(a)-(e)

The top management reviews on a yearly basis the performance of the QMS in light of Chapter 21 and the compliance of search and examination work with PCT Guidelines.

Any identified issues are discussed with the relevant departments and suitable solutions are proposed, evaluated and implemented. Consideration is given to any notes or feedback received from applicants and other offices. The QMS is annually reviewed by the Quality Department, HQC, together with the President of the EGPO to ensure compliance to the QMS requirements including those in Chapter 21 and the compliance of PCT search and examination work with PCT Guidelines.

During management review, all relevant QMS aspects are discussed, in particular, external or internal issues that may affect the QMs, status of achievement of quality objectives, feedback received from applicants and users of the patent system and also from relevant authorities, training needs and activities, the availability of appropriate resources, the adequacy of the quality policy, and opportunities for improvement.

Any identified issues are discussed with the relevant departments and suitable solutions are proposed for evaluation and then implementation.

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.

As part of the management review, EGPO's top management ensures all identified and expected risks and issues that might affect the QMS and the conformity of international search and examination are addressed and any opportunities for improvement are explored and pursued.

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).

Risk management is prevalent at all EGPO departments. EGPO identifies risks and opportunities through all processes in every department. Risks may come to light as issues with processes, training, human resources, policy, IT, office practice or quality, risks identified through work reviewing and applicants and users' feedback. There is a team composed of members from different office departments to identify potential risks, investigate and propose solutions to deal with them and follow up on their implementation with the respective department(s).

EGPO also has an approach to risk management in light of the quality requirements of the PCT International Search and Preliminary Examination Guidelines. The Quality Review Committee continuously monitors the risks encountered or expected to occur with the selected members in each department to continuously report on them and submit them to the High Quality Committee to discuss and put a plan to prevent re-occurrence. Identification and mitigation of risks lead to improvements in all EGPO processes. This could lead to including small changes, requiring only notification or minor training updates, or they could be large changes requiring new processes, or new system update.

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) In order to achieve the objectives of the quality policy and to meet the patent system users' expectations, EGPO continuously provides the required resources and focuses mainly on human resources.

Patent examiners:

- There are more than one hundred technical examiners in various technological fields. All
 examiners are Bachelor degree holders. About 30% of them hold Postgraduate Qualifications
 including Master's degrees and PhD.
- Many examiners have worked in their respective fields before joining the office and hence they have the necessary technological skills and expertise.
- EGPO examiners have the language skills to comprehend at least those languages meeting the minimum documentation requirement under PCT Rule 34. Examiners can process applications at least in Arabic and English. Some examiners are proficient in French.

Supportive actions:

- EGPO supports technical and legal examiners for IP Diploma study and IP Master Degree study inside and outside Egypt. There are currently more than 50 technical and legal examiners with IP post graduate degrees.
- Language courses (English and French) are also organized to enhance language skills.
- The Office makes an annual review and report to include in its future plan the need for further training for the staff and the need to employ new examiners in different fields of technology.

ii) Administrative staff:

EGPO places great emphasis on continued training of the administrative staff as well. It
organizes courses such as languages, computer skills, customer services, supervision skills,
archiving systems, modern documentation systems, administrative system development,
auditing and development of governmental affairs. Some administrative staff are also
supported to study IP Diploma.

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)

- EGPO is smoothly progressing infinalized executing the project "Improvement of EGPO IP Automation System" in cooperation with Korea International Cooperation Agency (KOIKA) planned forrun during the period of 2019-2023. The project aimeds to assist Egypt in building national competitiveness and a basis for sustainable development by improving the intellectual property administration framework and its automation system through the development of the electronic system service, equipment support, and invitational training. The project involved infrastructure and network renovation, and setting up systems for eservices and e-filing.
- Access points for Wi-Fi are available.
- Every technical examiner is equipped with a workstation consisting of a computer with 2 monitors and has an access to the internet.
- EGPO has updated almost all of the workstations in the office, and it performs a regular maintenance for the existing workstations.
- Technical examiners have access to various technology specific databases covering patent and non-patent literature and to commercial databases such as STN® and Reaxys®. Access also is available to the Egyptian Knowledge Bank.
- Concerning international applications, EGPO has become one of the countries that use e-PCT to create a paperless work environment in processing the international applications at the RO, ISA and IPEA stages. The processes managed through this system include:

electronic filing of international applications, receiving and storing all relevant documents from the applicants, handling and processing them according to the relevant PCT regulations and sending them to their destination, all under strict security. E-PCT helps EGPO to have data for calculating the workload of each examiner and technical section, and monitoring fluctuations in demand and backlog in a very transparent way.

 Technical examiners are now fully using the e-PCT portal to prepare and communicate the international reports.

(iv)

According to Rule 34 of the PCT Regulations, the Office has access to the full PCT minimum documentation through a variety of systems of internal and external databases, which are selected according to the needs of the particular international application.

(v) The PCT treaty, regulations and guideline, the Egyptian IP law, other treaties and conventions, search and examination guidelines and the internal instructions are accessible by all the staff via our internal network and in paper form. A search and examination manual is available and have undergone an update and revision process. Meetings are regularly conducted to discuss emerging issues and to ensure complete understanding and compliance with quality requirements.

A manual for examination of inventions in the biotechnology field has been developed, revised, and approved. It it will be published once all revision phases are finalized is currently available on EGPO website.

There is an e-PCT manual for the examiners. It includes three parts: a first part to guide the examiners on how to fill all ISA & IPEA forms in Arabic or English, a second part to guide the examiners on how to use e-PCT to upload Arabic forms or to complete the English forms online, and a third part to guide the examiners on how to deal with various cases on issues of clarity, unity, novelty, inventive step, and the optional use of "standardized clauses in each case.

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.

(vi)

To maintain a high level of competence, EGPO staff is involved in an ongoing training process.

Training Department:

- Training personnel are responsible of preparing different training programs and workshops for examiners and other target groups.
- EGPO have training rooms equipped with smart screens, laptop connected to data show and computer workstations connected to the office network and the internet.

Training for the new examiners:

- New examiners receive a general IP session to be familiar with all IP categories. Then, they are subjected to a general Patent course for one week which gives them an overview on the

patent system and the Egyptian law and the international treaties. After that a two weeks course on patent search and examination is delivered to the new examiners by senior examiners. Each examiner according to his/her specialty receives on job training for one month.

Training for all EGPO staff:

- All the EGPO staff is trained by the seniors and the Department Directors according to their specialties; besides, most of them receive some external training from other Patent Offices to enhance the staff qualifications and exchange experiences.
- EGPO technical and legal examiners receive training programs including on-job trainings which are conducted in the EGPO and also in cooperation with WIPO and other patent/IP offices to enhance their search and examination skills.
- All EGPO staff receives training on the procedures of the PCT patent application.
- All EGPO staff receives online distance learning courses supported by WIPO and EPO.

Training programs delivered by the EGPO trainers:

- Under cooperation between WIPO and ASRT a National IP Academy was established in Egypt. Qualified trainers organize and deliver patent and IP training courses in Egypt and other countries.
- EGPO examiners certified as IP trainers in the IP Academy, deliver yearly two Search and Examination Courses; one for African countries technical examiners and another one for Arab countries technical examiners.
- Most of them also tutor online distance e-learning courses in cooperation with the WIPO.

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.

(vii)

The head of HQC, together with the QRC and the Directors of all departments put in place plans for the resources required for the office departments within the budget and discuss it with the President of the EGPO.

In January 2020, EGPO started the EGPO EU Twinning Project: "Supporting and Upgrading the Institutional, Technical and Raising Awareness Capabilities of the Egyptian Patent Office (EGPO)". The project was successfully finalized in September 2022.

The overall objectives of the twinning project are to contribute to the improvement of the Egyptian economy and enhanced scientific research through better use of the patent system. The specific objective is to upgrade the institutional, technical and raising awareness capacities of EGPO

towards accepted international standards thereby leading to improved operations that attract more patent filings by Egyptian inventors, particularly in the scientific community.

The Twinning project provides provided support to EGPO in updating its processes and procedures to improve its performance and aligning them with the practices and standards of Patent Offices of Members of European Union, as well as to improve EGPO capabilities not only at institutional and technical level but also in its ability to raise awareness about the importance of Industrial Property as a tool to increase business competitiveness from the country.

The project included the following 5 components:

- Establishing IP Strategic plan for scientific research in Egypt;
- Establishing sustainable cooperation and coordination with right holders and SMEs within the institutional approach
- Utilizing newly installed state-of-the-art ICT and services;
- Increasing the level of EGPO staff training;
- Reforming patent processing and the organizational structure of the EGPO to a fully automated system, matching the best practices used in EU Member State patent offices.

The project is running smoothly and is expected to be finalized in May 2022. One of the most important aspects covered by the missions conducted in 2021 under the third component of the project was enhancing is the quality management system in EGPO and in particular discussing the preparations the collaboration with the Spanish Patents and Trademarks Office and the support provided to EGPO in preparation for obtaining for ISO 9001:2015 certification.

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.

(i) and (ii)

Features of the workflow automation system IPAS allow for the delivery, monitoring and follow up of applications by the reviewing examiners and the Director of the Technical Examination Department. They also facilitate monitoring and managing the workload in the department, a specific technical section, and for individual examiners. This is important upon the assignment and follows up of work to ensure the quality and timeliness and help dealing with backlogs in some sections.

Similar features are made available to examiners and Director of the Legal Examination Department.

Some actions in IPAS are now automated, such as those based on deadlines set by the law or regulations, e.g. withdrawal actions or actions based on applicant's reply to office actions within the set time limits.

Weekly and monthly reports of the input and output of the Technical Examination Department are prepared and presented to the Department Director to take the necessary actions if issues arise.

The Monitoring Department deals with workload and monitors timeliness and backlogs in each department. The department tracks the flow of all applications within the office departments to detect and report fluctuations and backlogs. All procedure and findings are reflected in a monthly report.

QRC can conduct an effective follow-up on IPAS, which follows the work of technical examiners and reviews the decisions of acceptance and rejection before transferring them to the legal department through specific actions on IPAS. They can return the report to the technical examiner if the committee finds any issues in the decision, which works to avoid issuing any decision that does not conform to the articles of the law.

Administrative systems are maintained to monitor all administrative tasks of EGPO as ISA/IPEA including processing of international applications for which EGPO serves as ISA, processing of demands for International Preliminary Examination, mailing of notices and communication of reports, and monitoring timeliness and pendency of reports. Through those systems, application status and workflow could be tracked.

A special follow up and tracking system deals with international applications to ensure timely processing, preparation of reports by examiners, mailing of notifications and communications are conducted efficiently and timely. The e-PCT system plays a major role in this respect. Currently, technical examiners prepare International Search Reports, Written Opinions and International Preliminary Examination reports and communicate them through e-PCT.

A monthly report on the processing of international applications for which international reports were issued is prepared reporting any issues for consideration by the QRC and HQC.

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.

(i) - (iii)

EGPO is working on activating an internal Quality Assurance system for self-assessment, and channeling the feedback to staff.

The supervisor of each technical section in the Technical Examination Department is responsible for checking the quality of the procedure of the national office actions and the international reports produced. The Director of the Technical Examination Department and Supervisors of technical sections are responsible for controlling of resources, providing guidance on work and harmonizing the practices among the different technical sections. The objective is to ensure that the same approach and practice is adopted in the search and examination of all patent applications, irrespective of which technical section performed the task.

There are 4 steps summarizing the quality assurance system:

- 1) Self-check by the examiner using a checklist, where the main criteria of quality are listed. There is special focus on lack of unity of invention, clarity and scope of claims, clear analysis of subject matter, documentation of search strategy, and classification.
- 2) Checking the procedures of substantive examination: the supervisor of each technical section reviews the technical reports.
- 3) For the international applications there is an additional check before issuing the ISR and the WOISA by the ISA/IPEA Unit personnel.
- 4) QRC performs quality checks on generated reports for national applications.
- To help examiners prepare reports more efficiently, samples from other offices have been collected and the most frequently used clauses have been made available to the examiners.

The Director of Technical Examination Department with Section Supervisors hold meetings with examiners to discuss recurring issues and discuss what is needed to improve the quality of the work.

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.

(a) - (c)

- 1) Ms. Eman S. Ibrahim Technical Examinar (<u>nawarah_noor@hotmail.com</u>)
- 2) Ms. Irini Girgis Technical Examinar (irinineseem@hotmail.com)

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) There is an allocated space for lodging complaints on the portal of the e-government. In addition, complaints and inquiries can be communicated directly to EGPO through e-mail, website, telephone or in person.

There are 3 levels at which an applicant or user can obtain feedback upon lodging a complaint:

- 1) Direct communication with the relevant examiner or administrative staff member either by meeting in person or through the phone. Most problems could be solved at this level.
- 2) Communication with a supervisor of the respective examiner or administrative personnel or if necessary the Director of the relevant Department.
- 3) If the issue was not resolved, the complaint would be handled under the direct supervision of the President of EGPO.

In all cases, EGPO ensures that response to complaints is timely. Suitable solutions are offered and implemented.

(ii) Patent agents, representatives of focal points and TISCs, and applicants are often invited to meetings to discuss their expectations and any notes on the quality of the products and services they receive. Clarification is provided and solutions are offered as required.

(iii) Clear and detailed information is available to the public on the EGPO website including the law and international treaties, national and international filing procedure, applicant guide, frequently asked questions, and other relevant information.

As part of the developments on EGPO's new website a dedicated space for SMEs is being created. It is intended to provide SMEs with relevant information on the patent system and how to file patent applications nationally and internationally. The SMEs space also is provided with SMEs toolbox which gives them support and allows them to access all relevant EGPO services. In addition, SMEs booklet is prepared to help SMEs to realize the importance of filing patent applications and how to get benefit from the patent system in supporting their business.

The EGPO applicant user guide was updated and uploaded on the website. Also, the Frequently Asked Questions section was revised and updated.

Some posters, brochures and infographics were prepared to be disseminated through the information desk and made available on the website.

Hard copies of the applicant guide and SMEs booklet are distributed in the various workshops and seminars conducted by EGPO for Universities, Research Centers and SMEs. The guide and booklet are also available for individual inventors and users.

Inquiries by applicants, inventors and patent agents are efficiently handled by the staff of the Receiving Office and the helpdesk providing general guidance and information. To handle specific technical or legal inquiries and provide more detailed guidance, technical and/or legal examiners are usually consulted. PCT Receiving Office is in continuous communication with PCT applicants offering special guidance to unrepresented individuals.

Applicants (especially if unrepresented) could request the guidance of a technical examiner in the respective technical filed for detailed guidance on writing the patent application before filing with the office. Discussions can also be scheduled after filing the application to provide clarification and guidance. Special advice and guidance is offered for students and representatives of SMEs before participating with their inventions in national or international exhibitions.

Regular meetings are conducted with the registered patent agents to discuss updates on procedures, fees, legal procedures and filing mechanisms e.g. use of e-PCT, e-filing and other eservices available. A number of e-services such as payment of translations and search fees can be processed and directly reflected on IPAS in the respective applications.

In addition, EGPO has many focal points all over Egypt to help applicants from universities, research institutions and industrial regions with filing their applications and to provide them with information about patent prosecution.

EGPO also provides training programs to officers of TISCs and Technology Transfer Offices (TTOs) to enhance their qualifications in providing relevant information to users and help them in drafting patent applications and performing patent searches.

(iv) Quality objectives are not currently available for the public.

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.

Representative from different EGPO Departments attend WIPO meetings regularly. Feedback is communicated to the respective Directors of Departments and HQC and QRC.

Concerning international applications, the EGPO is one of the countries that use e-PCT to create a paperless work environment in processing the international applications at the RO, ISA and IPEA stages. The processes managed through this system include: electronic filing of international applications, receiving and storing all relevant documents from the applicants, handling and processing them according to the relevant PCT regulations and sending them to their destination, all under strict security.

e-PCT helps EGPO to have data for calculating the workload of each examiner and technical section, and monitoring fluctuations in demand and backlog in a very transparent way.

Global Patent Prosecution Highway Agreements:

A number of bilateral agreements have been signed, e.g. between EGPO and CNIPA and also between EGPO & JPO to promote work sharing and enable patent applicants to request accelerated processing in the national phase, where Egyptian patent examiners can make use of the work products from the other Office(s). These work products can include:

The written opinion of the International Searching Authority,

The written opinion of the International Preliminary Examining Authority, or

The international preliminary examination report issued within the framework of the PCT, subject to certain conditions.

Reusing search and examination results in this way facilitates the prosecution of patent applications. The decision about whether to grant a patent, however, remains under the control of the respective national Office.

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.

(a)-(c)

The HQC prepares several documents which are required to ensure the quality of the national and international applications reports.

-As mentioned in section (1), the quality manual is under development. The documents required to finalize the quality manual are all available internally and include, among others; the Quality Policy, Quality Plan, Search and Examination guidelines, the structure of the quality report and the procedure for controlling the process.

These documents are available on the EGPO intranet and with the head of the HQC.

The latest versions of all these documents are available to all the EGPO staff which give them an overview on the quality procedure.

EGPO QMS includes documented information that is necessary for its effectiveness. In relation to search and examination work, these include in particular, the process cards, EGPO PCT Examiners Guidelines, EGPO Examination Guidelines for Biotechnological Patent applications, Department charts, manuals and forms, IP law and regulations, PCT treaty, regulation and examination guidelines, and other relevant treaties, regulations or manuals which are all made available to the staff through intranet/shared folders.

All documents necessary for the development of processes are included in the Internal Documentation Control List after the review of the respective Department Directors. Person(s) in charge of approving the documents are identified in this List.

Documents are identified by a special coding system.

Documentation Control List is located on the Intranet/Shared folder as placed by the IT Department personnel, which will also separate versions that have been canceled from the latest versions.

- 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.

(i)- (vi)

The QMS material includes the quality policy of EGPO with the statement from top management on commitment to the QMS. As indicated in the quality manual, the scope of the QMS covers both the filing, processing and registration procedures of national patent applications under the National Law on Intellectual Property Rights Protection (Law 82 of 2002) and the International Search of international patent applications, issue of search reports and preliminary examination reports on patentability in the framework of the work of international search and preliminary examination authorities under the Patent Cooperation Treaty. The material also includes the organizational structure of EGPO with all the departments and also the responsibilities and job descriptions of various personnel in each department.

Additionally, process cards and flow charts are available for all procedures and operations on national and international applications from reception until a final decision is reached. Information is also available on

The Quality manual under development will clearly indicate the quality policy of EGPO, highlight its objectives and state the commitment to the QMS. In addition, information on each of the following will be included: the scope of QMS, organizational structure and respective responsibilities of the different departments, documentation of all the conducted processes and procedures, the resources available to carry out the manual transfer of interactions between QMS processes in the various departments.

- 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) EGPO has these records on paper internal and external documentation control lists which are kept on the intranet. These records are not published and are stored in each concerned department as follows:
- (ii) Results of management review <u>and the meeting minutes are kept on the intranet after approval</u> by top management. <u>are submitted to EGPO President.</u>
- (iii) Records of all qualifications and training received are kept in the Training Department. Also, evaluation of the staff performance is made by Department Directors every year months.
- (iv) (v) All quality reports are analyzed and stored with the head of HQC-Quality Department both in a paper and electronic form.
- (vi) <u>- (vii) All process records, communications and search documentation for each application are kept in the application file and on the internal database (IPAS) for national applications. Process records of international applications are kept on the e-PCT.</u>

(vii)The entire examination process is entered and stored in our database.

(viii) - (xii) -These records are kept in the file of each application and a copy of Search and Examination reports are saved in the office internal database.

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)-(c)

Technical examiners attach to the submitted search and examination reports of each application a search process documentation including the databases consulted; the keywords with respective synonyms, search phrases, IPC symbols, and combinations thereof to form the search queries used; and the language(s) in which the search was conducted. Further, the examiners indicate the outline of their search process particularly the used search strategies. Search and Examination reports include, as appropriate, the relevant details about cases of limitation of search accompanied by clear reasoning, issues of the clarity of the claims, and lack of unity of the invention indicating justifications.

Currently, records on all the mentioned items are fully documented in paper form and partially documented in electronic form on the internal database.

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.

Initial Report on Quality Management Systems by The Egyptian Patent Office

21 11 January 202428 January February 20222023

page 29

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.

Annual reports will be prepared by the EGPO according to Chapter 21 and submitted to MIA.

[End of document]