

## **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 (EgPO)]*

*The Authority should provide general background information relevant to the quality management system (QMS) as set forth in this template.*

*The descriptions below each main heading of this template should be considered examples of the type and arrangement of information that should be included under each heading. Each Authority may provide additional information beyond that set forth in this template as desired.*

#### **INTRODUCTION (PARAGRAPHS 21.01 - 21.03)**

*If applicable, the Authority may at this point indicate any recognized normative reference or basis for their quality management system besides Chapter 21, such as ISO 9001, under the heading "Normative Reference for QMS"*

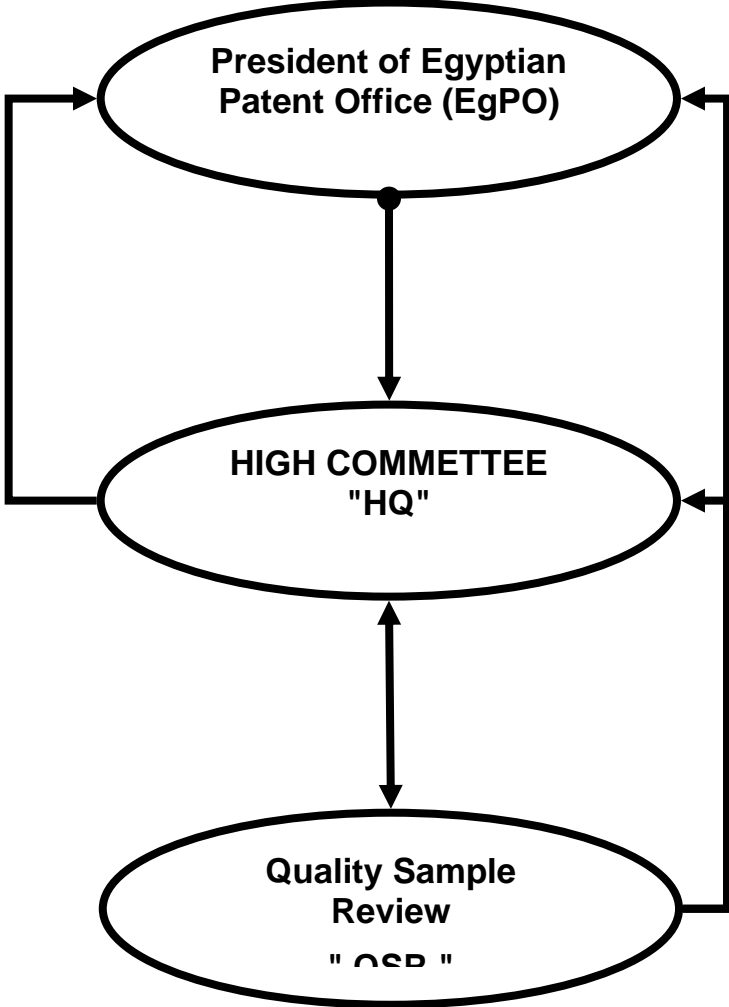
*For example: "Normative reference for QMS: ISO 9001, EQS (European Quality System)"*

*Each authority should then provide at least the information indicated in the descriptive boxes, under the following headings*

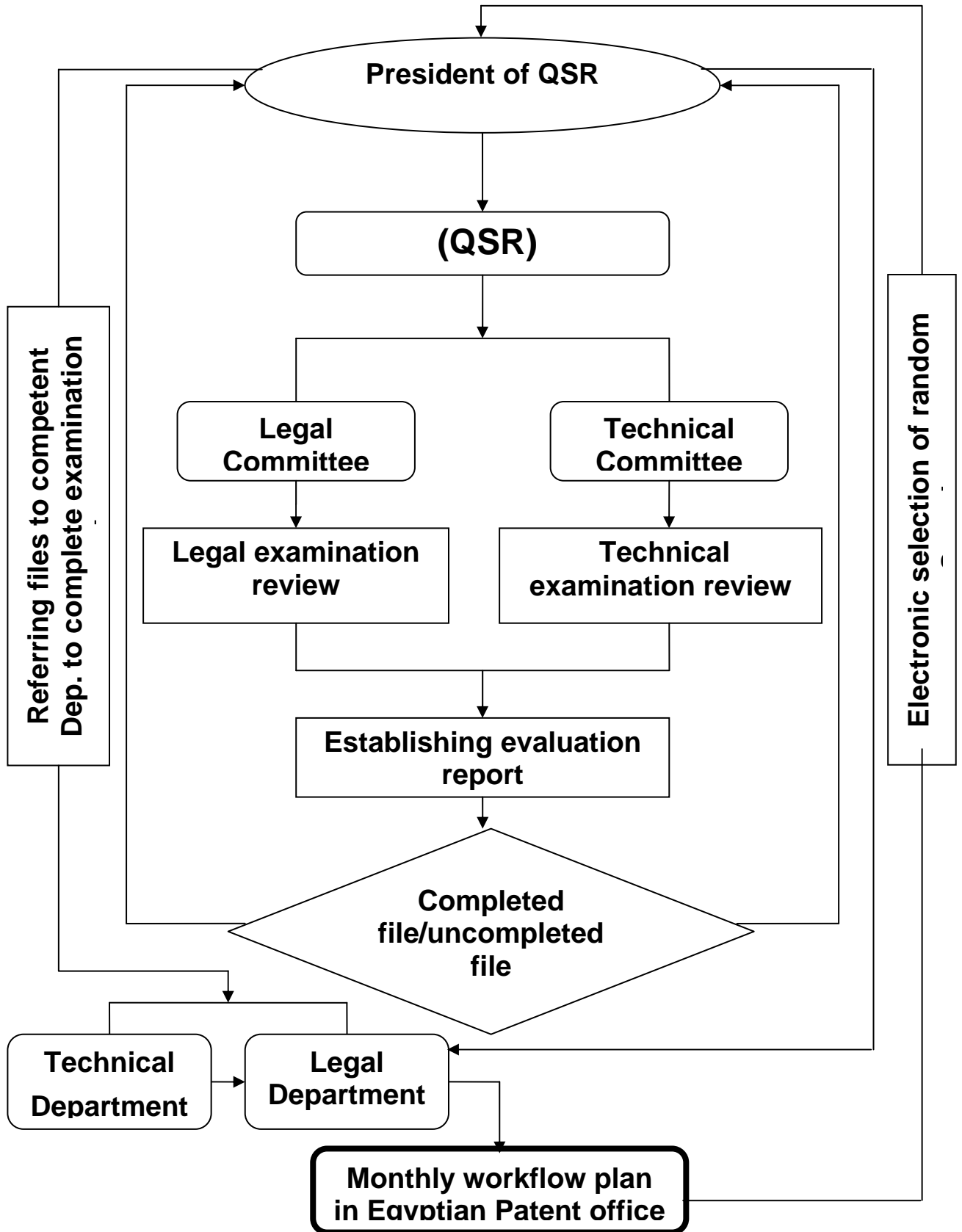
EgPO recognizes the importance of Quality Management System (QMS) to ensure that all patent processing steps are completed in a timely and high quality manner. The EgPO aims to maintain and improve its QMS as implemented for the PCT application processing according to chapter 21 of the PCT Search and Preliminary Examination Guidelines. The workflow of QMS and Quality Sample Review (QSRC) activities are summarized in the following schematics:

**EgPO workflow of QMS**

**QMS ( HIGH COMMETTEE "HQ" )**



### Quality Sample Review " QSRC "



Current activities for the QMS for the High Quality Committee (HQC) are:

- 1- Providing trained Human Resources to insure quality standards.
- 2- Providing the staff with latest training courses for insuring doing the work in a quality standards
- 3- Providing more equipments and updating networks for making S&E more easier.
- 4- Modernizing and providing our databases with updated information from the service providers.
- 5- Insuring doing work according to quality standards in each department.
- 6- Reviewing QSRC committee work for evaluating their performance.
- 7- Reviewing statistics for the performance of each department in order to evaluate their work.
- 8- Figuring out deficiencies in workflow, determining reasons for that and trying to put solutions.
- 9- Improving financial income via direct and indirect ways.

The (HQC) prepares a report and submits it to the President of the (EgPO) in order to put an action plan for implementing the recommendations of the committee .

During the intervals between the (HQC) meetings, the President of the (EgPO) holds a top management meeting with the head of the departments and gives directions to each department to stick to Quality standards.

In the next meeting, the (HQC) reviews the actual actions taken by the President of the (EgPO). The committee would also resume their activities.

### **Quality Sample Review Committee (QSRC)**

**The Purposes of QSRC:** To verify, validate, and monitor adherence to quality standards;  
To give feedback to the staff.

**QSRC Standers Resources:** PCT Search and Preliminary Examination Guidelines.

**QSRC structure:** QSRC has a total of 12 Examiners, 6 of them are responsible for legal examination, and the other 6 examiners are responsible for search and examination in different fields: Chemistry, Electricity, Agriculture, Civil Engineering, Chemical Engineering, and Pharmacology.

Patent Applications are sampled randomly at 10% and examination reports are collected for analysis according to quality standards. QSRC is responsible for establishing a mistake-correction system to prevent mistakes pertaining to legal and technical examination from recurring.

Once the (EgPO) starts its functions in the capacity of (ISA/IPEA), all the received PCT applications (International phase) will be reviewed.

## 1. LEADERSHIP AND POLICY

*21.04 Confirm that the following are clearly documented, and that this documentation is available internally:*

- (a) *The quality policy established by top management.*
- (b) *The roles and names of those bodies and individuals responsible for the QMS, as delegated by top management.*
- (c) *An organisational chart showing all those bodies and individuals responsible for the QMS.*

(a)

The quality policy of the QMS has been established by top management.

(b)

The Head of the High Quality Committee(HQC) is Mrs: Essmat Aly Abd Elatif – Acting President of the EgPO. Besides, there are two Technical examiners and two Legal examiners as members of this committee. They are:

- 1- Mrs: Mona Samaan – Chief chemists, Head of the Technical Department
  - 2- Mrs: Somaia Taher abd elmohsen – Chief Engineer in the Technical Department
- and
- 1- Mrs: Nival Mohamed Nabil – Manager of the Legal Department of (PCT)
  - 2- Mrs: Noha Mohamed Elsammad – Senior Legal Examiner.

(c)

The EgPO does not have a special Department for (QMS) in our administrative structure, but these Two committees, (HQC) and (QSRC), are considered a substitute for QMS. In addition, the Office Plans for the modernization and development of the efficiency of its work.

*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]

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		✓	

Chapter 21 requirement			Extent of compliance		
			full	part	no
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 throughout the Authority		✓	
21.09	(a)	Performance of a yearly internal review of the QMS in/to		✓	
	(b)	(i) determine the extent to which the QMS in based on Chapter 21		✓	
		(ii) determine the extent to which S&E complies with PCT Guidelines			✓
	(c)	an objective and transparent way		✓	
	(d)	using input incl. information according paragraph 21.17		✓	
	(e)	recording the results		✓	
21.10		Assurance to monitor and adapt to actual workload	✓		
21.11	(a)	Infrastructure in place to ensure that a quantity of staff		✓	
		(i) sufficient to deal with the inflow of work		✓	
		(ii) which maintains tech. qualifications to S&E in all technical fields		✓	
		(iii) which maintains the language facilities to understand languages according to Rule 34		✓	
	(b)	Infrastructure to provide a quantity of skilled administrative staff		✓	
		(i) at a level to support the technically qualified staff		✓	
		(ii) for the documentation records		✓	
21.12	(a)	(i) Ensuring appropriate equipment to carry out S&E	✓		
		(ii) Ensuring documentation accord. to Rule 34		✓	
	(b)	(i) Instructions to help staff understand and act accord. the quality criteria and standards		✓	
		(ii) Instructions to follow work procedures accurately and they are kept up-to-date.		✓	
21.13		(i) L&D program to ensure and maintain necessary skills in S&E	✓		
		(ii) L&D program to ensure awareness of staff to comply with the quality criteria and standards.		✓	

Chapter 21 requirement			Extent of compliance		
			full	part	no
21.14	(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		✓	
21.15	(a)	Control mechanisms to ensure timely issue of S&E reports		✓	
	(b)	Control mech. regarding fluctuations in demand and backlog			✓
21.16	(a)	Internal quality assurance system for self assessment		✓	
		(i) for compliance with S&E Guidelines		✓	
		(ii) for channeling feedback to staff		✓	
	(b)	A system for measurement of data and reporting for continuous improvement		✓	
	(c)	System for verifying the effectiveness of actions taken to correct deficient S&E work	✓		
21.17	(a)	Contact person helping identify best practice between Authorities	✓		
	(b)	Contact person fostering continual improvement	✓		
	(c)	Contact person providing for effective comm. with other Authorities for feedback and evaluation	✓		
21.18	(a)	(i) Appropriate system for handling complaints	✓		
		(ii) Appropriate system for taking preventive/corrective actions		✓	
		(iii) Appropriate system for offering feedback to users		✓	
	(b)	(i) A procedure for monitoring user satisfaction & perception		✓	
		(ii) A procedure for ensuring their legitimate needs and expectations are met		✓	
	(c)	Clear and concise guidance on the S&E process for the user		✓	
	(d)	Indication where and how the Authority makes its quality objectives publicly available			✓
21.19		Established comm. with WIPO and desig. + elected offices	✓		
21.20		QMS of Authority clearly described (e.g. Quality Manual)			✓
21.21	(a)	Documents making up the Quality Manual have been prepared and distributed			✓
	(b)	Media available to support the Quality Manual			✓
	(c)	Document control measures are taken			✓

Chapter 21 requirement			Extent of compliance		
			full	part	no
21.22	(a)	Quality policy of the Authority and commitment to QMS			✓
	(b)	Scope of QMS			✓
	(c)	Organizational structure and responsibilities			✓
	(d)	the documented processes are carried out in the Authority			✓
	(e)	Resources available to carry out processes			✓
	(f)	a description of the interaction between the processes and the procedures of the QMS.			✓
21.23	(a)	Records which documents are kept and where they are kept	✓		
	(b)	Records of results of management review	✓		
	(c)	Records about training, skills and experience of staff		✓	
	(d)	Evidence of conformity of processes		✓	
	(e)	Results of reviews of requirements relating to products		✓	
	(f)	Records of the S&E process carried out on each application	✓		
	(g)	Record of data allowing individual work to be tracked		✓	
	(h)	Record of QMS audits			✓
	(i)	Records on actions taken re. non-conforming products			✓
	(j)	Records on actions taken re. corrective actions			✓
	(k)	Records on actions taken re. preventive actions			✓
	(l)	Records referring to search process documentation	✓		
21.24	(a)	(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		✓	
	(b)	Records about other information relevant to the search		✓	
	(c)	(i) Records about limitation of search and its justification		✓	
		(ii) Records about lack of clarity of the claims		✓	
		(iii) Records about lack of unity			
21.25		Report on its own internal review processes		✓	
21.26-21.28		Additional information on further inputs to its internal reviews			✓
21.29		Initial report called for by paragraph 21.19	✓		



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) and (b)

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

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)

There is a meeting held by the President of the (EgPO) with the managers to discuss performance reports and emphasize the importance of adhering to quality standards at work.

21.08 *Indicate how and when top management of the Authority or delegated officers:*

- (a) *conducts management reviews and ensures the availability of appropriate resources;*
- (b) *reviews quality objectives; and*
- (c) *ensures that the quality objectives are communicated and understood throughout the respective Authority.*

(a) and (c)

A High Quality Committee (HQC) holds meetings according to the Quality Management Standards set out in chapter 21 of the PCT Search and Preliminary Examination Guidelines. The committee has to hold at least one meeting a year with top management to review the performance of its quality management system.

(b)

There is no automatic system for reviewing of quality objectives.

21.09 *Indicate whether top management or delegated officers of the Authority perform an internal review of the QMS in accordance with paragraphs 21.25-21.28:*

- (a) *at least once per year (cf. paragraph 21.25);*
- (b) *in accordance with the minimum scope of such reviews as set out in Section 8, namely:*
  - (i) *to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.25, 21.27(a));*
  - (ii) *to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.25, 21.27(a));*
- (c) *in an objective and transparent way (cf. paragraph 21.25);*
- (d) *using input including information according to paragraphs 21.27 (b)-(f);*
- (e) *recording the results (cf. paragraph 21.28).*

(a)

The last meeting was held last year and the next meeting is planned to be held this year .

(b)

(i) The (QSRC) have Records for the applications it have reviewed from the Search & Examination (Technical & Legal) point of view.

(ii), (c) and (d)

The (QSRC) renders a report on each application; if it finds no compliance with PCT Guidelines (national phase), it gives a feedback to the examiner who has performed that task in order to modify his decision.

(e)

Results of QSRC (on Search and Examination work) are recorded.

## 2. Resources

*21.10 Explanatory note: The granting of ISEA 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 to Sections 21.11 to 21.14, below, should provide this assurance.*

*21.11 Human resources:*

- (a) Provide information about the infrastructure in place to ensure that a quantity of staff:
  - (i) sufficient to deal with the inflow of work;*
  - (ii) which maintains the technical qualifications to search and examine in the required technical fields; and*
  - (iii) 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.**
- (b) Describe the infrastructure in place to ensure that a quantity of appropriately trained/skilled administrative staff is maintained and adapted to changes in workload:
  - (i) at a level to support the technically qualified staff and facilitate the search and examination process;*
  - (ii) for the documentation of records.**

(a) (i),(ii),(iii) and (b)

Each year the Office makes his annual review and report and put in its future plan the need for future training for the staff and the need to employ new examiners in different fields of technology. After that, there will be an intensive training to prepare the staff for work. Besides, the Office provides training courses for improving the staff language skills, not only for the new employees, but for the whole staff as well.

The EgPO has updated about 70% of the PCs in the office, and it renders a regular maintenance for the existing PCs.

*21.12 Material resources:*

- (a) *Describe the infrastructure in place to ensure that*
  - (i) *appropriate equipment and facilities such as IT hardware and software to support the search and examination process are provided and maintained;*
  - (ii) *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.*
- (b) *Describe how instructions*
  - (i) *to help staff understand and adhere to the quality criteria and standards, and*
  - (ii) *to follow work procedures accurately and consistently*

*are documented, provided to staff, kept up-to-date and adapted when necessary.*

(i) Every examiner is equipped with a workstation consisting of a computer with an access to databases and Internet.

(ii) The EgPO provides an access to internal and external databases for every examiner, and now we are about to accomplish the requirements of Rule 34 PCT.

(b).

(i) (ii) The PCT, the Egyptian law for the protection of IPRs no. 82/2002, other treaties and conventions, the Guidelines and the internal instructions are accessible by all the staff via our database and on paper.

*21.13 Training resources:*

*Describe the training and development infrastructure and program which ensures that all staff involved in the search and examination process:*

- (i) *acquire and maintain the necessary experience and skills; and*
- (ii) *are fully aware of the importance of complying with the quality criteria and standards.*

(i), (ii)

All the examiners are trained indoor by the seniors and the managers according to their specialists; besides, most of them receive a sort of external training from other Patent Offices to improve their skills in using special programs.

The technical report from the first examiner is reviewed by the Seniors and approved by the head of the department to ensure high work quality.

*21.14 Oversight over resources:*

*Describe the system in place for continuously monitoring and identifying the resources required:*

- (a) *to deal with demand; and*
- (b) *comply with the quality standards for search and examination*

(a) (b)

The President of EgPO, together with Human Resource and IT departments, put plans for the resources required for the office within our flexible budget.

### 3. Management of administrative workload

21.15 *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:*

- (a) *Effective control mechanisms regarding timely issue of search and examination reports to a quality standard as set by the respective Authority; and*
- (b) *Appropriate control mechanisms regarding fluctuations in demand and backlog management.*

(a) and (b)

There is a monitoring department for our workload which prepares a Monthly report on our work and it also monitors timeliness and backlogs in each department.

### 4. Quality assurance

21.16 *The following are required quality assurance measures for timely issue of search and examination reports of a quality standard in accordance with the Guidelines. Indicate how the following are implemented:*

- (a) *An internal quality assurance system for self assessment, involving verification, validation and monitoring of searches and examination work:*
  - (i) *for compliance with these Search and Examination Guidelines;*
  - (ii) *for channelling feedback to staff.*
- (b) *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.*
- (c) *A system for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes, and to prevent issues from recurring.*

(a) (i),(ii) The office has not fully reached the stage of e-work yet. But the examiners are working now according to the manual for S&E on the national phase. After starting to work as ISA/IPEA, we will deal with the PCT International Phase according to its guidelines. Then, we will work on activating an internal quality assurance system for self assessment, and channeling the feedback to staff.

The first examiner's technical report is reviewed by the Seniors and approved by the head of the department to ensure high work quality.

Also, the QSR committee selects randomly 10% of the applications, whether accepted or refused, each month to ensure the continuous improvement of the examination process.

Besides, the Media Department collects the reports from each department monthly to render an overall statistic.

(b) and (c)

We are planning for implementing quality assurance electronically, but for now we are doing it manually.

## 5. Communication

### 21.17 Inter-Authority communication:

*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)

Both:

- 1- Eng: Hanaa Mohamed Ahmed Abdallah el Dakrory – As Chief chemist- Technical Department.
- 2- Mr: Marwan Said Yousef – Senior Legal Examiner – Legal Department

### 21.18 Communication and guidance to users:

*Describe the system in place for monitoring and using customer feedback including at least the following elements:*

- (a) *An appropriate system for*
  - (i) *handling complaints and making corrections;*
  - (ii) *taking corrective and/or preventative action where appropriate; and*
  - (iii) *offering feedback to users.*
- (b) *A procedure for:*
  - (i) *monitoring user satisfaction and perception; and*
  - (ii) *for ensuring their legitimate needs and expectations are met.*
- (c) *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.*
- (d) *An indication of where and how the Authority makes its quality objectives publicly available for the users.*

(a) (i) Complaints are handled by President of EgPO, together with the head of the concerned department

(ii) We can take any necessary action for helping within our applicable law

(b) (i) (ii) The office invites patent attorneys and applicants to meet for discussion in order to be aware of their needs.

(c) In our website, there are useful information and guidance for the users to help them apply for a patent.

In addition, the EgPO joins national and international exhibitions in the company of our inventors to present their inventions. Also, the EgPO has many focal points all over Egypt to help applicants from universities, searching institutions and industrial regions submit their applications and to provide them with information about the examination process .

(d) It is not available for the public.

**21.19 Communication with WIPO and designated and elected Offices:**

*Describe how the Authority provides for effective communication with WIPO and designated and elected offices. In particular describe how the Authority ensures that WIPO feedback is promptly evaluated and addressed*

The EgPO attend WIPO meetings regularly.

**6. Documentation**

**21.20 Explanatory note:** *The QMS of the Authority needs to be clearly described and implemented so that all processes in the Authority and the resulting products and services can be monitored, controlled, and checked for conformity. This is done in the documents that make up the Quality Manual of the Authority (see paragraph 21.21).*

*(Note: This point is informative. No response is required by the template to paragraph 21.20)*

**21.21** *The documents that make up the Quality Manual serve to document the procedures and processes affecting the quality of work, such as classification, search, examination and related administrative work. In particular, the Quality Manual indicates where to find instructions on the procedures to be followed.*

*For the purposes of this report indicate:*

- (a) the documents making up a Quality Manual that have been prepared and distributed;*
- (b) the media on which it is supported (e.g. Internal Publication, Internet, Intranet); and*
- (c) document control measures taken e.g. version numbering, access to latest version.*

(a-c) Uptill now, we do not have a manual for quality.

**21.22** *Indicate whether the documents making up the Quality Manual include the following:*

- (a) the quality policy of the Authority including a clear statement of commitment to the QMS from top management;*
- (b) the scope of the QMS, including details of and justification for any exclusions;*
- (c) the organizational structure of the Authority and the responsibilities of each of its departments;*
- (d) 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;*
- (e) the resources available for carrying out the processes and implementing the procedures; and*
- (f) a description of the interaction between the processes and the procedures of the QMS.*

(a-f) The EgPO future vision is to get ISO9001.

21.23 *Indicate which types of records the Authority maintains, such as:*

- (a) a definition of which documents are kept and where they are kept;*
- (b) results of management review;*
- (c) training, skills and experience of personnel;*
- (d) evidence of conformity of processes, resulting products and services in terms of quality standards;*
- (e) results of reviews of requirements relating to products;*
- (f) the search and examination processes carried out on each application;*
- (g) data allowing individual work to be tracked and traced;*
- (h) records of QMS audits;*
- (i) actions taken re. non-conforming products, e.g. examples of corrections;*
- (j) actions taken re. corrective action;*
- (k) actions taken re. preventative action; and*
- (l) search process documentation as set out in Section 7.*

(a) The EgPO has these records on paper. These records are not published and are stored in each concerned department as follows:

(b) Results of management review are submitted to the EgPO President

(c) Records of all qualifications and training received are kept in the Human resources Department. Also, evaluation of the staff performance is made by the line manager every year.

(d) The technical reports are regularly reviewed until issuing the final decisions.

(e) –

(f) All communications and search documentation for each application are kept inside the application file.

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

(h-k) –

(i) These records are kept in the file of each application.

## 7. Search process documentation

21.24 *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:*
  - (i) *limitation of search and its justification*
  - (ii) *lack of clarity of the claims; and*
  - (iii) *lack of unity.*

(a)-(c)

The Examiners have to render a search process documentation in the search & examination reports attached to the file of each application, and they have to indicate how their searches are performed (strategy) .Now we are going to modify our search and examination report to comply with the international form standards to make it more easier for examiners.

## 8. Internal review

21.25 *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.*

21.26-21.28 *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*

## 9. Arrangements for Authorities to Report to the MIA

21.29 *There are two stages in the reporting arrangements. The document up to this point relates to the initial report called for by paragraph 21.29. It will be supplemented annually by further reports in accordance with paragraph 21.30.*

[End of document]