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Patent Cooperation Treaty (PCT)

Common Quality Framework for International Search and Preliminary Examination

REPORT ON QUALITY MANAGEMENT SYSTEMS

Prepared by [TURKISH PATENT INSTITUTE]

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 %Jormative 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

TPI has established a Quality Management System (QMS) covering all of services regarding patent granting procedures. The QMS covers the processing of PCT applications both in the international phase and international searches. The QMS is fully operational in effect. First PCT applications are expected due in April 2017.

TPI has acquired ISO 9001 certification (TS EN ISO 9001: 2015) on 28 April 2016 and ISO 27001 certification procedures are continuing as a normative reference for QMS;

- ✓ to increase the effectiveness of the QMS,
- ✓ to understand the customer's quality requirements,
- ✓ to define the areas need to be improved necessary for the quality issues
- ✓ to keep information assets secure,
- ✓ to enhance customer satisfaction, and to achieve continual improvement of its performance.

The quality objective of TPI is to prepare high quality search and examination reports in a timely manner. TPI already has well-established quality management systems for national patent granting procedures.

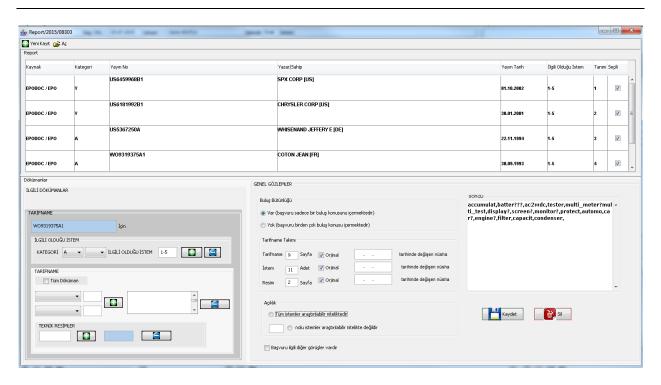
From its foundation in 1994, TPI has already implemented major quality assurance measures which includes; customer satisfaction, effective and productive communication with stakeholders, internal discussion platform, well-functioning IT infrastructure and software to track each process regarding patent applications, search and examination guidelines.

Within the context of customer satisfaction, the well-trained call center staff is ready to answer the questions from users promptly and helping them to find solutions to their needs. TPI is always accessible via its web site (www.tpe.gov.tr) for every kind of information related to protection from filing to grant such as, regulations, laws, informative documents, application guidelines, etc.

Each year, in order to maintain effective and productive communication with stakeholders, TPI organizes regular consultative meetings in which the management of TPI is present to exchange views on the current practice with patent attorneys and users. In these meetings, patent attorneysq feedbacks are also taken regarding the search and examination products and services.

TPI has a very efficient internal communication structure, thanks to the discussion platform. The complicated issues are discussed in periodical meetings. The final decisions are recorded, categorized and accessible to every examiner via the intranet. This is how harmonization of practice is applied. Guidelines for search and examination are available for both TPI examiners and external users via the website of TPI (www.tpe.gov.tr). Decisions of the discussion platform and courts are taken into consideration for the self-assessment and revision of the Search & Examination Guidelines.

TPI has a well-functioning IT infrastructure and software to track each process regarding patent applications through the Patent File Management Software (PATUNA). TPI has also QMS S&E Report Management Program, which provides recording of various data regarding the search and examination process such as, the databases consulted, the keywords, combinations of words and truncations used, the language(s) in which the search was carried out, the classes and class combinations searched according to the IPC, categories of prior art documents and the list of all search statements used in the databases consulted.



The Quality Management Manual has been prepared and TPI has implemented the QMS for all of the services regarding patent granting procedures and covering the processes of PCT applications both in the international phase and international searches. As of now TPI has put into place an internal quality assurance system in compliance with 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 delegated by top management.
- (c) An organizational chart showing all those bodies and individuals responsible for the QMS.
- (a) The Quality Policy is established by the top management.

The Quality Policy is;

- TPI provides services of the highest quality to the utmost satisfaction of patent applicants and attorneys.
- TPI commits itself to achieve reliable, consistent, fair and transparent search and examination reports based on regulations, laws and treaties.
- TPI ensures the granting patents in a timely manner to contribute to the patent systems and technological developments.
- TPI maintains cooperative relationships with patent applicants and attorneys to get efficient feedback to enhance the quality and effectiveness of its search and examination report processes.
- TPI commits itself to improve its quality of services through continuous training and increasing the level of knowledge and capabilities of patent examiners.

The quality policy is first prepared as a draft by the patent department and officially approved by the top management, and reviewed periodically during internal reviews. The quality policy is published in the intranet.

(b)

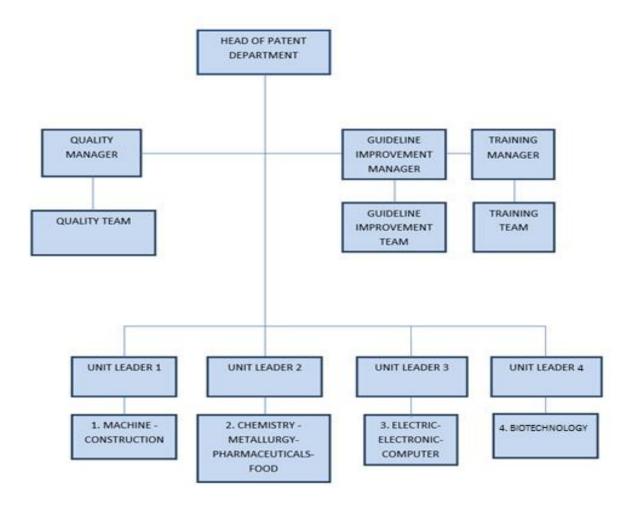
Quality manager: Quality Manager is responsible for all the quality issues of the patent examination process. The Quality Manager is appointed from a senior patent examiner who have a great deal of knowledge and high level of expertise in quality matters. The Quality Manager in coordination with the unit leaders analyses the results of the quality control and gives feedback on the results to the top management. Quality manager together with the unit leaders is involved in preparing and establishing the quality procedures. Quality Manager reviews customer requirements and makes sure that they are met by the patent examiners. Quality Manager is Kemal Demir Eralp (MBA, Senior Patent Examiner).

<u>Unit leaders</u>: Unit leaders are responsible for all matters regarding quality in their respective units. Unit leaders check the search and examination reports by selecting randomly, to check whether these reports conform to laws, regulations and the Search & Examination Guidelines. Moreover, unit leaders give feedback on the results to quality manager. Unit Leader 1 (Machine . Construction) is Dr. Ali R²za Köker, Unit Leader 2 (Chemistry . Metallurgy . Pharmaceuticals . Food) is Serkan Özkan (LLM), Unit Leader 3 (Electric . Electronic . Computer) is Mustafa Güney Çal² kan and Unit Leader 4 (Biotechnology) is Pharm. D Ay e Göksu Kaya Özsan (PhD candidate).

Quality team: All unit leaders together form the quality team.

(c)

QUALITY MANAGEMENT SYSTEM (QMS) ORGANISATIONAL CHART



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]

Chapte		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	21.05 Established compatibility of QMS with Chapter 21		√			
21.06	21.06 (a) Mechanisms to ensure effectiveness of the QMS		✓			

Chapter 21 requirement						e:e
				full	part	no
		(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		√ 1	
		(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		√ 1	
		(b)	(i) determine the extent to which the QMS in based on Chapter 21		√ 1	
			(ii) determine the extent to which S&E complies with PCT Guidelines		√ 1	
		(c)	an objective and transparent way		√ 1	
		(d)	using input incl. information according paragraph 21.24		√ 1	
		(e)	recording the results		√ 1	
21.10			Assurance to monitor and adapt to actual workload	✓		
	(i)		Infrastructure in place to ensure that a quantity of staff	√		
		(a)	sufficient to deal with the inflow of work	✓		
		(b)	which maintains tech. 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 records	√		
	(iii)		Ensuring appropriate equipment to carry out S&E	✓		
	(iv)		Ensuring documentation accord. to Rule 34	✓		
	(v)	(a)	Instructions to help staff understand and act accord. 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	√		

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¹ The first internal review of the performance of the QMS shall take place in 2017.

Chapter 21 requirement						e
				full	part	no
		(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	√		
21.11	(i)		Control mechanisms to ensure timely issue of S&E reports	✓		
	(ii)		Control mech. regarding fluctuations in demand and backlog	✓		
21.12	(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	√		
21.14		(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	√		
21.15	(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	✓		
	(iv)		Indication where and how the Authority makes its quality objectives publicly available	√		
21.16			Established communication with WIPO and designated and elected Offices	✓		
21.17			QMS of Authority clearly described (e.g. Quality Manual)	√		
21.18		(a)	Documents making up the Quality Manual have been prepared and distributed	√		
		(b)	Media available to support the Quality Manual	√		
	1	(c)	Document control measures are taken	√	1	

Chapte	er 21 rec	uirement		ent of plianc	е
			full	part	no
21.19	(i)	Quality policy of the Authority and commitment to QMS	✓		
	(ii)	Scope of QMS	✓		
	(iii)	Organizational structure and responsibilities	✓		
	(iv)	the documented processes are carried out in the Authority	✓		
	(v)	Resources available to carry out processes and implementing the procedures	√		
	(vi)	a description of the interaction between the processes and the procedures of the QMS.	√		
21.20	(i)	Records which documents are kept and where they are kept	✓		
	(ii)	Records of results of management review		√ ²	
	(iii)	Records about training, skills and experience of staff	✓		
	(iv)	Evidence of conformity of processes		✓2	
	(v)	Results of reviews of requirements relating to products		√2	
	(vi)	Records of the S&E process carried out on each application	✓		
	(vii)	Record of data allowing individual work to be tracked	✓		
	(viii)	Record of QMS audits		✓2	
	(ix)	Records on actions taken re. non-conforming products		√ 2	
	(x)	Records on actions taken re. corrective actions		√ 2	
	(xi)	Records on actions taken re. preventive actions		✓2	
	(xii)	Records referring to search process documentation	✓		
21.21	(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	✓		

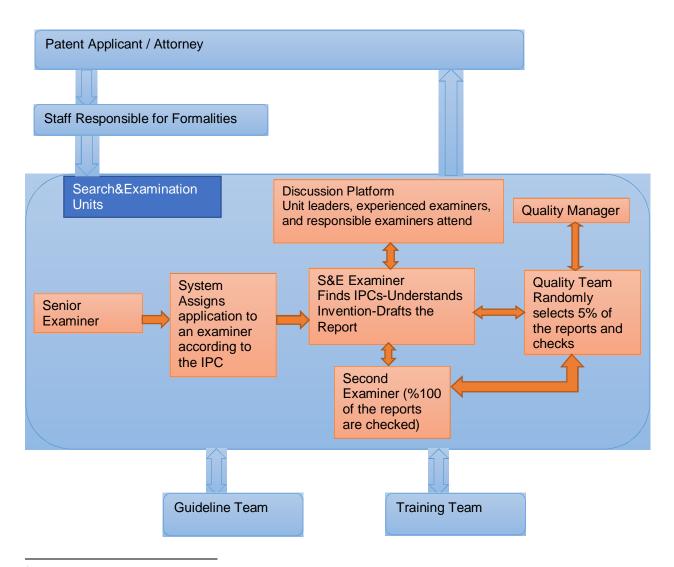
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 $^{^{2}}$ The records shall be generated and the results will be reviewed after first QMS internal review in 2017.

					Extent of compliance		
				full	part	no	
21.22			Report on its own internal review processes		√ 3		
21.23- 21.25			Additional information on further inputs to its internal reviews		√ 4		
21.26			Initial report called for by paragraph 21.26	✓			

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 progress



³ Report on the QMS internal review processes shall be prepared after the first QMS internal review in 2017.

⁴ After first QMS internal review in 2017, additional information on the QMS internal review processes shall be determined.

The quality manager and the quality team are together responsible for improving the QMS and ensuring its effectiveness. To ensure the effectiveness, the quality team holds yearly meetings and evaluates all the data such as unit leadersq reviews, user complaints and objections, deficiencies in search and examination, survey results and comments from the meetings with attorneys/applicants. Results of the yearly meetings are evaluated and corrective/preventive actions are taken accordingly. Also to improve the effectiveness of the QMS, meetings with the guideline and training team+are held. If necessary, quality manager and quality team may revise QMS and discuss these revisions with management.

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.

TPI management holds meetings at least once a year with all the staff about the functioning of TPI. In these meetings, the annual performance of the patent department presented by the head of patent department and the objectives of the oncoming year are discussed. Suggestions, complaints and comments, not only about the process of search and examination, but also anything about TPI such as the treaty and regulatory requirements may be expressed by the examiners and other staff.

Also surveys and questionnaires are conducted by the management to determine the satisfaction of patent examiners and other staff.

Moreover, the performance of each examiner is evaluated and the new yearly based goals per examiner are determined. The importance of fulfillment of the QMS requirements is reminded to the staff. In extraordinary circumstances, the management may also organize additional meetings regarding quality issues. All staff is always notified via e-mail.

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

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

The management meets regularly about the sufficiency of human resources and IT infrastructure in accordance with the quality objectives.

At the beginning of each year the quality manager together with the quality team reviews the results of the previous year regarding the quality objectives. If necessary, the management shall revise or modify the quality objectives accordingly.

Guideline team revises the TPI Search & Examination Guideline according to previous years quality check results. If there is any change in the regulations and laws, the guideline team is responsible for updating the TPI S&E Guideline. Decisions of the discussion platform and the courts are also taken into consideration for the self-assessment and revision of the Guidelines.

Training team ensures the increase of the knowledge and capacity of the examiners through carefully planned training programs. The newly employed examiners are subjected to comprehensive and intense training programs. The experienced examiners are also subjected to training programs for getting familiar of the new practices and for keeping their information updated.

The management communicates the revised objectives to the staff during periodical meetings, trainings and the revised quality objectives are available on the intranet. All staff is also always notified via e-mail.

21.09 Indicate whether top management or delegated officers of the Authority perform an internal review of the QMS in accordance with paragraphs 21.22-21.25:

- (a) at least once per year (cf. paragraph 21.22);
- (b) in accordance with the minimum scope of such reviews as set out in Section 8, namely: to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.22, 21.24(i)); to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.22, 21.24(i));
- (c) in an objective and transparent way (cf. paragraph 21.22);
- (d) using input including information according to paragraphs 21.24 (ii)-(vi);
- (e) recording the results (cf. paragraph 21.25).

The quality manager together with the quality team prepares review reports every three months. The TPI top management holds meetings at least once a year with the quality manager, in which the review reports are evaluated.

Each review report contains quality records regarding all the search and examination activities recorded by the unit leaders. The review report also contains the evaluation and effectiveness of the quality management system.

Furthermore, the quality team evaluates S&E processes and examinersqactivities in compliance with the PCT Guidelines. First audit will take place in 2017. The working group of PCT Search and Examination guideline has revised the existing guideline of TPI in accordance with PCT guideline. The TPI (S&E) guideline may also be accessed to the public via online (http://www.tpe.gov.tr).

2. RESOURCES

21.10 Explanatory note: The granting of ISA/IPEA status means that the Authority has demonstrated it has the infrastructure and resources to support the search and examination process. Chapter 21 calls for assurance that the Authority can continually support this process while accommodating changes in workload and meeting QMS requirements. The responses below, should provide this assurance.

Human resources:

(i) Provide information about the infrastructure in place to ensure that a quantity of staff: sufficient to deal with the inflow of work;

which maintains the technical qualifications to search and examine in the required technical fields; and

which maintains the language facilities to understand at least those languages in which the minimum documentation referred to in Rule 34 is written or is translated

is maintained and adapted to changes in workload.

(ii) Describe the infrastructure in place to ensure that a quantity of appropriately trained/skilled administrative staff is maintained and adapted to changes in workload:

at a level to support the technically qualified staff and facilitate the search and examination process, and

for the documentation of records.

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.

In TPI, patent examiners are responsible for S&E activities. All patent examiners have at least Bachelors Degrees. 47% of examiners have Master Degrees or PhD Degrees or are candidates. TPI has the capacity for preparing search and examination reports in all technical fields. 100% of patent examiners have good knowledge of English and 12% of patent examiners also have the knowledge of third language such as German and French. TPI recruits examiners after a three stage (including foreign language) examination in accordance with their technical knowledge.

As of 2016, TPI has 112 full time examiners in total. All examiners receive training sessions to improve their knowledge in the PCT system. The latest PCT training was given by the Korean

Patent Office in September 2016. TPI is planning to acquire 50 new examiners by the end of 2018.

TPI has the latest technology in IT hardware such as twin 24+full HD monitors for all examiners and the IT software is continuously being improved in accordance to the needs and necessities to provide most effective services.

IT and patent department communicates regularly for necessary IT software updates and hardware requests. Workload of the examiners is being monitored by the software. TPI meets the PCT minimum documentation criteria. We have access to the following databases;

- (a) EPOQUENet, incorporating access to Derwent World Patent Index (DWPI);
- (b) Commercial databases such as IEEE Xplore, Elsevier, Springer
- (c) Turkish national patent database (PATUNA), Turkish Scientific and Technological Research Council databases including EBSCOhost (with 375 full-text databases, a collection of 600,000-plus ebooks, subject indexes, point-of-care medical references, and an array of historical digital archives),
- (d) STN, including BIOSIS, CAPLUS, Embase, MEDLINE, American Chemical Society (ACS) database,
- (e) Free databases such as; EMBL-EBI (European Molecular Biology Laboratory European Bioinformatics Institute), the ChEMBL interface that permits also searches based on formulacs drawing, and NCBI (National Center for Biotechnology Information).

All necessary information can be accessed through the Intranet such as PCT Guidelines, training documents, documents related to quality management system (quality reports, checklists, manual, etc.).

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.

TPI provides trainings in Patent Law, Formal Examination, Substantive Examination, Novelty, Inventive Step, Industrial Applicability, Unity, Clarity, Databases (EPOQUENET, ESPACENET, etc.), Classification Systems (IPC, CPC), and Language Courses. Also, examiners should take WIPO and EPO distance learning courses.

		TOPIC	DURATION	
			- Introduction	
		- Patent law		
	General Introduction		- Granting procedures	2 Weeks
			- Patent software of TPI	2 vveeks
BASIC TRAINING		- Databases		
		- International Agreements		
	External	- Distance Learning Courses		
	Sources	- Seminars organised by EPO		

		D • C			
		- Basic Concepts	_		
		- Classification			
	Introduction to Search	- Scope of patent	1 Week		
	to Scaren	- Search strategies			
		- Case studies			
		- Basic Concepts			
		- Sufficiency of disclosure			
	Cl	- Unity	1 3371-		
	Clarity / Unity	Clarity / Unity	- Clarity	1 Week	
		- Complex Cases			
		- Case studies			
SEARCH AND EXAMINATION	How to Draft Search Reports	- Basic Format			
RELATED		- Document Categories			
TRAINING		- Extra Cases	1 Week		
		- Analysis of claims (Feature Table)			
		- Case studies			
		- Introduction			
	EpoqueNet		TO	- Basic Queries / Search Strategies	1 Wash
		- Documents selection/view/print	1 Week		
		- Case studies]		

		TOPIC	DURATION
		- Basic Concepts	
		- Prior Art	
SEARCH AND	Novelty -	- Grace Period	1 Wools
EXAMINATION RELATED	Inventive Step	- Evaluation	1 Week
TRAINING		- Evaluation of Inventive Step	
		- Case studies	
	External Sources	- Distance Learning Courses	
		- Seminars Organised by EPO	
	On the job training	 Competency based training by experienced examiners and using practical work 	3 Months
	Physics / Mechanics	- Novelty - Inventive Step	2 Weeks
INTERMEDIATE LEVEL	Electronic	- Clarity	2 Weeks
EE v EE		- Unity	2 Weeks
ADVANCED	Periodical	- Case Studies	4 times/year
LEVEL	Works	- Discussion Platforms	2 times/year

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	Special Courses (Not	- Distance Learning Courses	
	related with S&E)	- Seminars Organised by EPO	
	PCT Related		
OTHER	Issues		1 Week
OTHER	Language		
	trainings	- French, German, or other	on request

Oversight over resources:

(vii) Describe the system in place for continuously monitoring and identifying the resources required:

to deal with demand; and

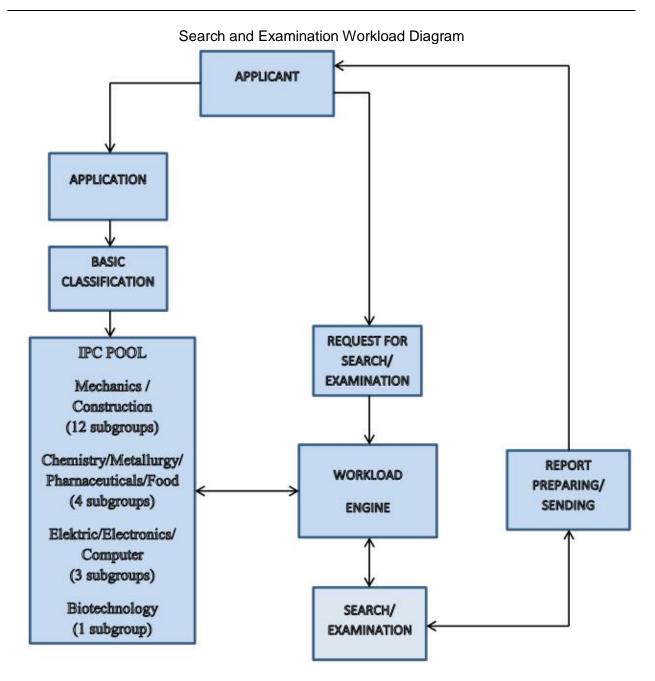
comply with the quality standards for search and examination.

The number of patent applications in all technical fields is periodically monitored to identify the trends. According to the estimated number of applications in all technical fields, necessary number of examiners are determined and then recruited.

3. MANAGEMENT OF ADMINISTRATIVE WORKLOAD

- 21.11 Indicate how the following practices and procedures for handling search and examination requests and performing related functions such as data-entry and classification are implemented:
 - (i) Effective control mechanisms regarding timely issue of search and examination reports to a quality standard as set by the respective Authority; and
 - (ii) Appropriate control mechanisms regarding fluctuations in demand and backlog management.

After application is filed, the application is basically classified as a first step by senior patent examiners. The applications are then assigned to appropriate examiner by the workload engine. This software distributes the workload equally and also monitors fluctuations in demand of each technical fields and backlog management by checking the number of assigned workload. This software also monitors the time limits for preparing report according to each examiner and reports the delays if any.



4. QUALITY ASSURANCE

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

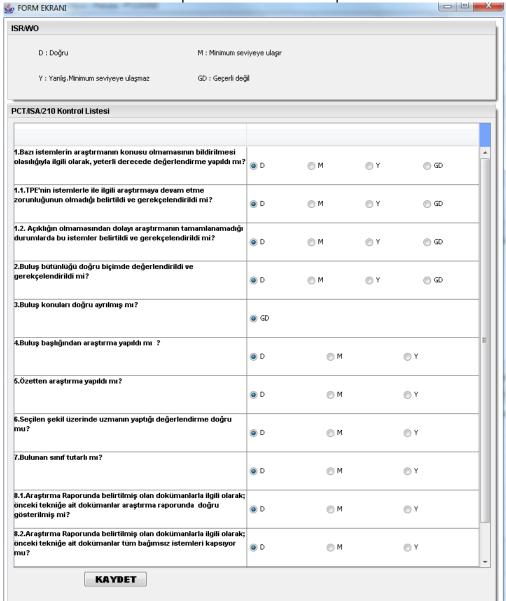
(i) An internal quality assurance system for self-assessment, involving verification, validation and monitoring of searches and examination work:

for compliance with these Search and Examination Guidelines;

for 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.

In the quality control process, all reports are checked by a second examiner in order to ensure the correctness of all the reports before issuing them. The second examiner checks the reports according to the checklist. The second examiner ensures that the report meets the requirements of the checklist. The second examiner controls the reports according to the correctness of the IPC code(s), whether all claims are searched or not, keywords used, correctness of codes (X, Y, etc.) and whether the standard specified sentences and phrases are used in the report.



After quality control, the second examiner confirms the quality of the report and only after then the report is sent to applicant by the first examiner. However, if any deficiency is found by the second examiner, the second examiner sends back the feedback to the first examiner who prepared the report. After the report is revised by the first examiner, the second examiner checks the revised report once again and confirms if the deficiency is eliminated. All reports sent to the applicants are signed by the first examiner once report is cleared by quality control.

In the Quality Assurance process, each month 5% of all the reports which were issued to applicants after the quality control process (second examiner check) are being controlled

(compliance to pre-determined time limits, the correctness of the IPC code(s), whether all claims are searched or not, keywords used, correctness of codes (X, Y, etc.) and whether the standard specified sentences and phrases are used in report and databases used) by the quality team. Reports are selected by the sampling method. All results are recorded and reported periodically. Reports are being evaluated and corrective actions are taken by the quality team and quality manager.

Also, discussion platform handles difficult cases and establishes standards for each case. Quality manual is periodically revised accordingly and all examiners are informed about the revisions. In addition, feedback from users is an essential input for taking necessary precautions and revisions of the quality manual.

PDCA cycle is being used in patent search & examination. In the \$\mathbb{M}\text{lan+phase}\$, objectives are set according to applicants needs. In \$\mathbb{M}\text{o+phase}\$, plans are implemented. In \$\mathbb{M}\text{check+phase}\$, results are analyzed and in \$\mathbb{M}\text{ct+phase}\$, quality of the service is improved.

5. COMMUNICATION

Inter-Authority communication:

21.13 Explanatory note: Each Authority should provide for effective communication with other Authorities.

(Note: This point is informative. No response is required by the template to paragraph 21.13)

- 21.14 Provide the name, job title and contact details of the Authorities designated quality contact person who will take responsibility for:
 - (a) helping identify and disseminate best practice among Authorities;
 - (b) fostering continual improvement; and
 - (c) providing for effective communication with other Authorities to allow for prompt feedback from them so that potential systemic issues can be evaluated and addressed.

The quality manager is responsible for the quality issues on patent search and examination processes. The quality manager is also responsible for helping identify and disseminate best practices among Authorities which also includes providing the effective communication with other Authorities.

At the time of the appointment, the quality manager and the contact person of TPI with other authorities is Kemal Demir Eralp (kemal.eralp@tpe.gov.tr), senior patent examiner. Quality manager is also certified by the Turkish Standard Institution (TSI).

Communication and guidance to users:

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

(i) An appropriate system for

handling complaints and making corrections;

taking corrective and/or preventative action where appropriate; and offering feedback to users.

(ii) A procedure for:

monitoring user satisfaction and perception; and

for ensuring their legitimate needs and expectations are met.

- (iii) Clear, concise and comprehensive guidance and information to users (particularly unrepresented applicants) on the search and examination process, giving details of where it is to be found e.g. link to Authority web site, guidance literature.
- (iv) An indication of where and how the Authority makes its quality objectives publicly available for the users.

Complaints are recorded by a software and classified/analyzed by dedicated personnel. All complaints are evaluated by the quality team. In the case of an error, corrective actions are taken and the decisions are notified to the complainant.

Surveys are one of the most important components in determining user satisfaction and efficiency of the quality management system. For this reason, TPI encourages users to fill in the surveys. To meet usersqueeds, TPI organizes meetings with applicants and attorneys periodically. The last meeting was held on 2 September 2016.

Search & Examination Guideline is published in the TPI web site. Also training courses are organized about %understanding search and examination reports+ for applicants and patent attorneys.

The TPI website includes information about ‰w to apply for international PCT applications, PCT guidelines and PCT regulations. Also useful information such as applications fees, forms and some samples can be viewed through the website.

21.16 Communication with WIPO and designated and elected Offices:

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

The Quality Manager is also responsible for communication with WIPO and designated and elected Offices.

At the time of appointment, the quality manager and the contact person of TPI with WIPO is Kemal Demir Eralp (kemal.eralp@tpe.gov.tr), senior patent examiner.

6. DOCUMENTATION

21.17 Explanatory note: The QMS of the Authority needs to be clearly described and implemented so that all processes in the Authority and the resulting products and services can be monitored, controlled, and checked for conformity. This is done in the documents that make up the Quality Manual of the Authority (see paragraph 21.18).

(Note: This point is informative. No response is required by the template to paragraph 21.17)

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

For the purposes of this report indicate:

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

Documents making up the Quality Manual has been prepared and distributed to the staff. Document control measures such as version numbering are taken and the latest version is published internally. All documents are available on the intranet.

- 21.19 Indicate whether the documents making up the Quality Manual include the following:
 - (i) the quality policy of the Authority including a clear statement of commitment to the QMS from top management;
 - (ii) the scope of the QMS, including details of and justification for any exclusions;
 - (iii) the 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.

The quality manual includes the quality policy, the scope of the QMS, the organizational structure, the documented processes carried out in the Authority, the resources necessary for carrying out the processes and interaction between the processes.

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

- (i) a definition of which documents are kept and where they are kept;
- (ii) results of management review;
- (iii) training, skills and experience of personnel;
- (iv) evidence of conformity of processes, resulting products and services in terms of quality standards;
- (v) results of reviews of requirements relating to products;
- (vi) the search and examination processes carried out on each application;
- (vii) data allowing individual work to be tracked and traced;
- (viii) records of QMS audits;
- (ix) actions taken re. non-conforming products, e.g. examples of corrections;
- (x) actions taken re. corrective action;
- (xi) actions taken re. preventative action; and
- (xii) search process documentation as set out in Section 7

Quality manager and the quality team are responsible for keeping records of management review, training of personnel, evidence of conformity of processes, results of reviews relating to search and examination reports, the search and examination processes carried out on each application, data allowing individual work to be tracked and traced, actions taken in case of non-conformities, corrective actions and preventative actions and documentation of search process.

7. SEARCH PROCESS DOCUMENTATION

21.21 For internal purposes the Authority should document its search process.

The Authority should indicate

- (a) which of the following are included in this record:
 - (i) the databases consulted (patent and non patent literature);
 - (ii) the keywords, combinations of words and truncations used;
 - (iii) the language(s) in which the search was carried out;
 - (iv) the classes and class combinations searched, at least according to the IPC or equivalent;
 - (v) a listing of all search statements used in the databases consulted.
- (b) which other information relevant to the search itself is included in this record e.g. a statement of the subject of search; details of special relevance to internet searching; a record of documents viewed; on-line thesaurus, synonym or concept databases, etc.

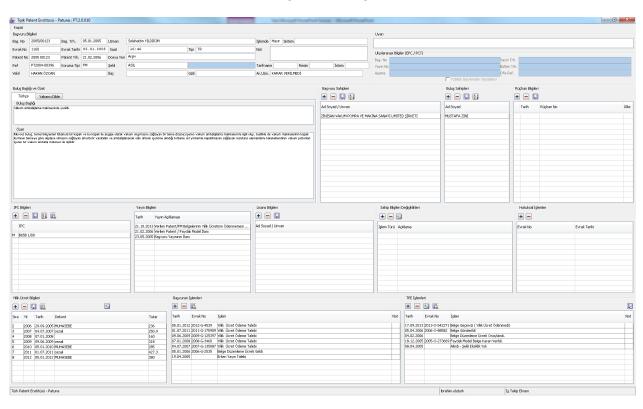
(Explanatory note: The IA is requested to list other information it may collect to monitor and improve the search process)

- (c) which special cases are documented and whether records are kept denoting any:
 - (vi) limitation of search and its justification
 - (vii) lack of clarity of the claims; and
 - (viii) lack of unit

The IT system named as Patent File Management System (PATUNA) provides carrying out the procedures and recording of each step regarding the patent search and examination processes as well as formalities from filing to grant.

TPI is a paperless office with more than 95% of their applications online. Every physical application is scanned so that full text search by the Patent File Management Program (PATUNA) is available.

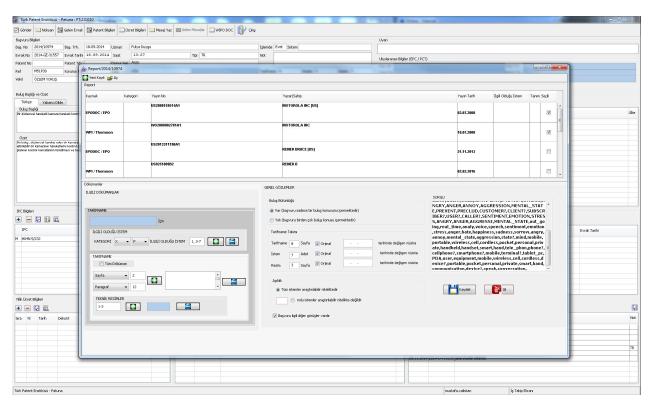
With the help of the Patent File Management Program (PATUNA), all the information about the patent application is recorded such as; application number, date of application, applicant and inventor, priority, IPC classes, publication, all communications between applicant and TPI, the fees, whole changes in transactions. The data registered in PATUNA, facilitates analysis and statistical assessment of all the process from filing to grant or refusal of the application.



Patent File Management Program (PATUNA)

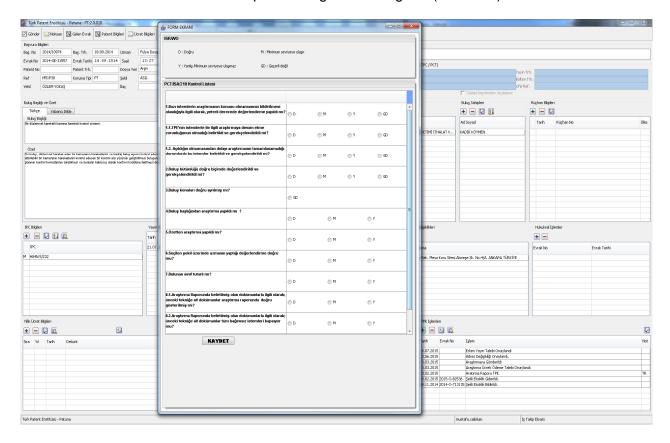
TPI has also the QMS S&E Report Management Program, integrated with PATUNA, which records and documents search and examination process in accordance with the QMS. The QMS S&E Report Management Program records the databases consulted, the keywords, combinations of words and truncations used, the language(s) in which the search was carried out, the classes and class combinations searched according to the IPC and the list of all search statements used in the databases consulted. QMS S&E Report Management Program also records the special cases such as lack of clarity and unity of claims.

QMS S&E Report Management Program makes it possible for the second examiner to control the search and examination reports with the help of check list. The results of the second examiners check list is recorded and is available for further assessment for future feedback during the evaluation of the examiners work. By this way, the systematic errors, common problems and lack of knowledge in certain areas are detected and these data is considered during the decision making on training needs or areas for improvement. The data registered in QMS S&E Report Management Program, facilitates analysis and statistical assessment of the search and examination process.



QMS S&E Report Management Program

QMS S&E Report Management Program (Checklist)



8. INTERNAL REVIEW

21.22 Explanatory note: The Authority should report on its own internal review arrangements. These reviews determine the extent to which it has established a QMS based on the model of Chapter 21 and the extent to which it is complying with the QMS requirements and the Search and Examination Guidelines. The reviews should be objective and transparent to demonstrate whether or not those requirements and guidelines are being applied consistently and effectively and should be undertaken at least once a year. With reference to point 21.08 of this template, the Authority may provide additional information on its internal review arrangements under this section if it so wishes.

21.23-21.25 These arrangements are reported according to this template in Section 1, above, at points 21.04 - 21.09. The Authority may provide additional information on further inputs to its internal reviews under this section, if it so wishes

9. ARRANGEMENTS FOR AUTHORITIES TO REPORT TO THE MIA

21.26 There are two stages in the reporting arrangements outlined in Chapter 21: the initial report called for by paragraph 21.26(a), and supplementary annual reports in accordance with paragraph 21.26(b). At the second informal meeting of the Quality Subgroup in Canberra on February 6 and 7, 2012, the Subgroup recommended that, instead of submitting full reports every five years and cumulative updates in the intervening years, Authorities should submit each report in the form of a full report, making the differences from the previous years report clear, for example using % cack changes + or other form of highlighting. The template for the supplementary annual reports is therefore no longer used.

[End of document]