

PATENT COOPERATION TREATY (PCT)

Common Quality Framework for International Search and Preliminary Examination

INITIAL REPORT ON QUALITY MANAGEMENT SYSTEMS

prepared by Japan 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)

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

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 JPO has developed its "JPO's Vision" as a mission to be carried out, making it available to the public on the JPO's website. A quality policy at the Patent Examination Departments, however, has not been established yet.

(b)

The Deputy Commissioner is in charge of supervising and organizing important matters related to technologies among various operations involving examinations, appeals, and trials; and has responsibility for the QMS.

(c)

Organisational chart (Figure 1) is posted on the Quality Management Office's website on the intranet.

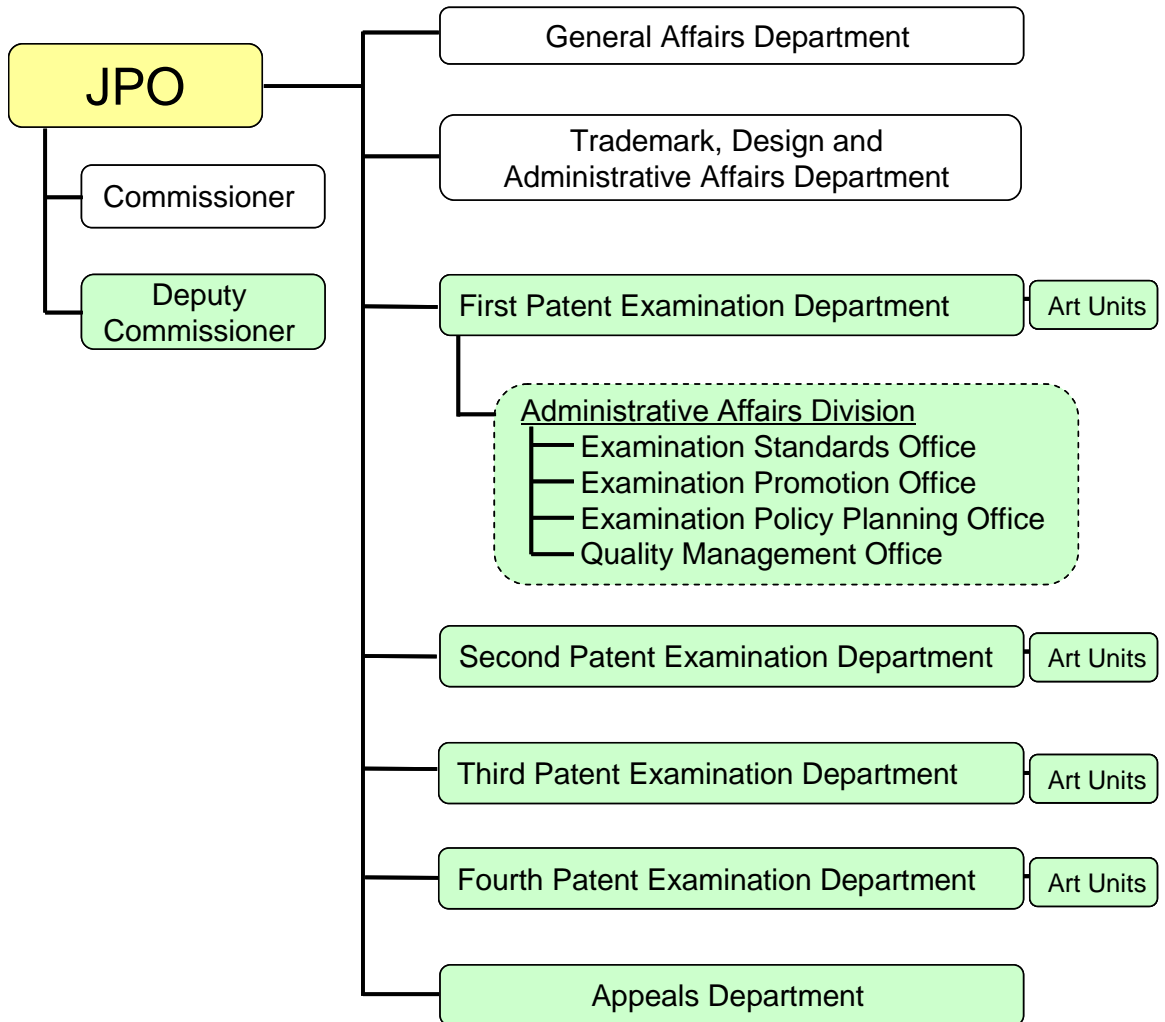


Figure 1 Organisational chart

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.

Chapter 21 requirement			Extent of compliance		
			full	part	no
21.04	(a)	Quality policy available		✓	
	(b)	Identified roles and names for QMS responsibility	✓		
	(c)	Organisational 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 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	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
		(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.	✓		
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 channelling 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	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
	(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	✓		
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		✓	

Chapter 21 requirement			Extent of compliance		
			full	part	no
		(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)(b)

The JPO's quality management system (QMS) includes activities to improve the quality of patent examination at the Patent Examination Departments with regard to substantive patent examination including search and examination work of PCT applications. These activities on quality are planned in the sections concerned, discussed at the Meeting of the Deputy Commissioner and the Director-Generals of the first through fourth Patent Examination Department and Appeals Department (MDCDG), and decided by the Deputy Commissioner.

The Quality Management Office (QMO) bears responsibility for measuring and analysing the results of patent examination work and the related feedback from users. In addition, it is responsible for reporting the results of these analyses to MDCDG.

MDCDG reviews the QMS based on the results from QMO and other input it receives (See 21.09). The Deputy Commissioner makes decisions to improve the effectiveness of the QMS and its processes.

The JPO ensures the effectiveness of the QMS and its processes, based on the mechanism described above.

For example, in order to improve the quality of patent examination work, several examiners consult with each other and share know-how on search strategies, etc. In addition, directors check the search and examination work at each Art Unit where applications of each technical field are examined. Based on these activities, the JPO strives to ensure that proper examinations of each individual case are achieved in order to unify examiners' practices.

In terms of activities for measuring and analysing, QMO manages internal reviews of individual cases that are reviewed by third parties in the JPO. And in addition collects and analyses User Satisfaction Surveys and related statistical information. The internal reviews

are carried out by a committee that serves as a third party and consists of three directors from each Patent Examination Department. Thus, 12 directors plus a chairperson make for a total of 13 committee members. The results from the analyses by the committee are presented to MDCDG and the sections concerned should take these results into consideration in forging plans to improve processes related to quality. These results and measures are provided to the Art Units.

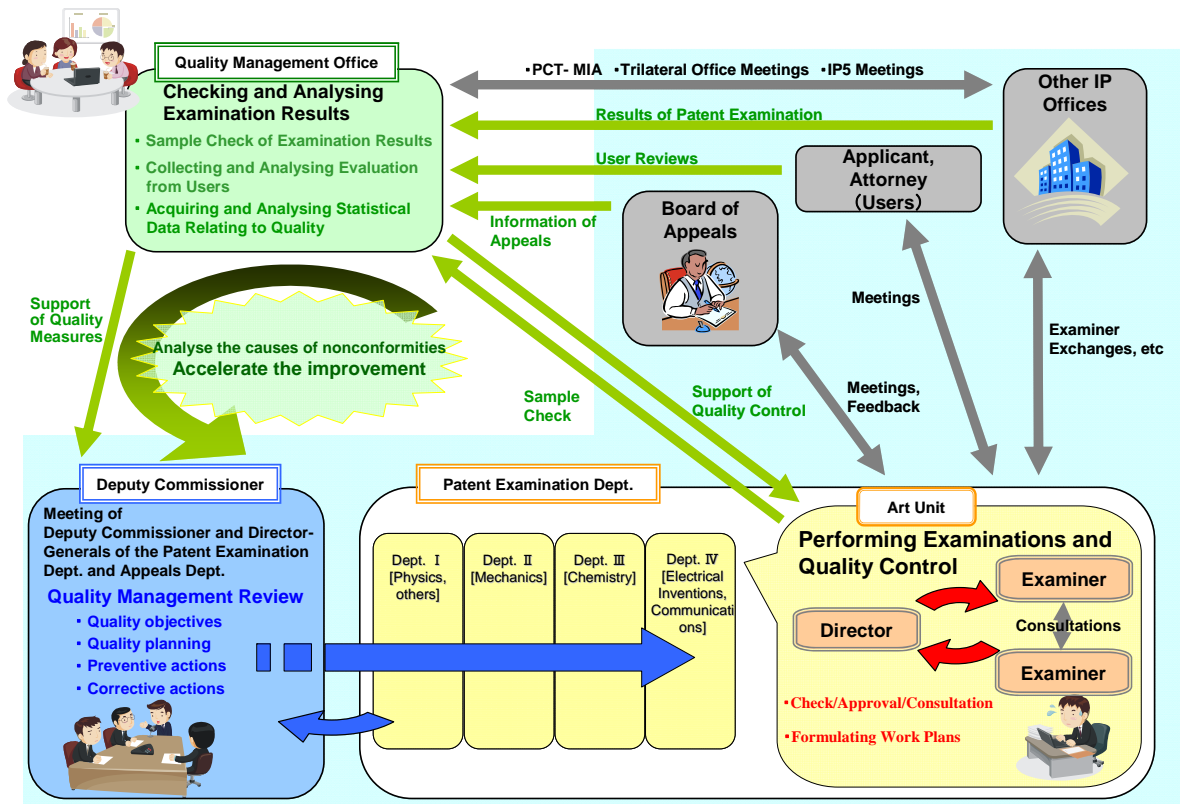


Figure 2 Mechanism ensuring the effectiveness of the QMS and its processes

21.07 Indicate how management of the Authority communicates to its staff the importance of meeting treaty and regulatory requirements including:

- those of this standard; and
- complying with the Authority's QMS.

(a)(b)

At the beginning of fiscal year, the Deputy Commissioner reviews and revises the handling target of examination including quality objectives at MDCDG and the handling target of examination is widely notified to all staff.

Through this notification, the JPO communicates to its staff the importance of meeting quality standard and compliance with the JPO's QMS.

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)

The Deputy Commissioner conducts management review on human resources, physical resources and educational resources, if necessary, at MDCDG being held once or twice a week.

(b)(c)

See 21.07

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 Deputy Commissioner conducts management review of the QMS at MDCDG held once or twice a week, if necessary. In addition, a comprehensive management review of the QMS is carried out at the end of fiscal year.

(b)(d)

The input to the management review includes:

- Results of review of sampled cases (See 21.16(a));
- Statistical data related to quality (See 21.16 (b));
- Feedbacks from users (See 21.16(b));
- Corrective actions and preventive actions taken for detected or potential non-conformities discovered through the above;
- Status of corrective actions and preventive actions;
- Follow-up actions from previous management reviews;
- Recommendations for improvement of the QMS.

(c)(e)

The results of these reviews are recorded in the meeting documents and are notified to staffs.

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)

In the JPO, patent examiners carry out search and examination. These patent examiners generally have a technical educational background from universities or colleges and have a bachelor's degree at least, and there also are examiners with master's degree or doctor's degree. The JPO recruits examiners from applicants who passed the first class national public servant recruitment examination, in the divisions of science and engineering or agriculture. The examination is ranked as the most difficult among national public servant recruitment examinations. Furthermore, the successful applicants undergo a character test and their nature is carefully evaluated.

English is one of the subjects in the first class national public servant recruitment examination. The JPO regards English ability as an essential element in recruitment of its staff. Moreover, assistant examiners are required to receive specified English language training course before they are promoted to examiners. They can also participate in training courses for other foreign languages such as French, German, Korean, Chinese, etc.

As a provisional measure to cope with further increasing backlogs, the JPO has employed highly specialized outside human resources as fixed-term examiners for five years. The JPO gave an examination, equivalent to the first class national public servant recruitment examination, to strictly evaluate their nature, and employed them.

As of FY2011, the JPO retains 1711 examiners in total (fixed-term examiners, 490).

(b)

Part of staff at of office work and management divisions is examiners from Patent Examination Divisions, and they sufficiently know about PCT system. Other staff also has received appropriate trainings on the whole PCT system, search/examination process, and contents of operations.

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.

(a)

(i)

Resources include a system for effectively executing searches of prior art documents such as minimum documentation, and a drafting system for implementing international searches and international preliminary examinations. These resources are extremely important for examiners to perform their task, and are periodically updated, and are upgraded upon their request when needed. Technical support is also extended to examiners so that the best operating conditions are continuously maintained.

With searches for a prior art, the JPO has developed its own system, which searches not only through IPC or Full text in Japanese and English but also through commercial Web such as STN and JDreamII, which can be executed by a single PC terminal for examiners. Access to Japanese and foreign patent documents, as well as NPL (Non Patent Literature), is possible from this terminal. For retrieval of foreign patent documents, search using IPC, ECLA and USPC is possible.

There are many search systems originally developed by the JPO. They include: the F-term system (which is based on classification with multiple viewpoints) and the FI system (which is the IPC fine-tuned by the JPO). Therefore, examiners can choose an appropriate search tool according to the content of an application.

The following is a concrete description of the F-term system: Under the F-term system, about 2,600 technical groups (theme codes) are defined; and for about 1,800 technical groups, "terms" which are multiple viewpoint classifications suitable for each technical group are assigned. Persons with profound knowledge of both technology and patents have previously analyzed the Japanese patent and utility model documents and have assigned an appropriate "terms". Therefore, with the F-term system a more precise search is available than searches by using key words, etc. In addition, F-term, FI, IPC and key words can be used simultaneously so that a quick and extremely precise search is executed. With respect to NPL about computer software and NPL about intensively competitive field or advanced technical field that are unable to be searched by commercial database, the JPO has

developed its own database. Computer software terms like F-term are assigned to the documents on the computer software database so it is possible to search a document with these terms.

Furthermore, a search formula used in searches and a document set obtained by the search formula can be automatically recorded, search know-how can be shared among examiners.

When an examiner establishes International Search Reports or International Preliminary Examination Reports, report preparation support by drafting system has been realized. Especially, innovations to prevent drafting mistakes, such as mounting of functions to permit simultaneous drafting of necessary documents, a function of automatic import of bibliographic matters to drafting documents, a checking functions for input contents, etc are provided. Moreover, electronic management and electronic approval procedure for PCT applications are realized.

The office management divisions analyze the functions and the performance of the information systems and the systems are reviewed every year. Measures for their improvement are designed to meet the requirements of examiners, in order to provide comfortable environments where the examiners can execute the highest quality searches and preliminary examinations with maximum efficiency.

(ii)

The JPO possesses a substantial amount of documentation, mainly comprising patent documents. With respect to Patent documents, the JPO along with the National Center for Industrial Property Information and Training possesses all official gazettes corresponding to minimum documentation, and the JPO's examiners are able to utilize these gazettes (For most part of the official gazettes of the minimum documentation, examiners are free to access those documents from their terminals). For NPL, the JPO is able to utilize published magazines and commercial on-line databases including JDreamII etc., thus, it secures to access a wide range of NPL, making it possible to meet the requirements for minimum documentation.

(b)(i)(ii)

➤ "PCT International Search and Preliminary Examination Guidelines"

English and Japanese versions are provided for examiners in the form of paper media. This can be available through the intranet.

➤ Manuals for internal practices

Basic practices for examiners to carry out international searches and preliminary examinations are documented in internal manuals. These are distributed to examiners in the form of paper media. It can be referred to through the intranet. These internal manuals comprehensively describe matters from criterion of judgment for international searches and preliminary examinations to procedures on internal system. They are based on rules and regulations such as the Treaty, the Regulations and the Guidelines and the operational procedure of the internal system (PCT-RO).

➤ Computer System Operations Manuals

These can be referred through the intranet.

➤ Useful Information to Improve Quality

Useful information to improve quality is seen at the site of QMO on the intranet.

All of the above instructions are available from the Portal Site of Examination Department on the intranet. The site of QMO is linked from the Portal Site. These documentations are updated if necessary.

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.*

➤ Course training

An officer recruited by the JPO is required to attend three training courses and pass the examinations for each course before becoming an examiner. Total hours of three courses are 250 hours. Lecturers for this training program include university professors, lawyers and examiners. The training programs include training in the international regulations, together with related rules including the Patent Cooperation Treaty, the contents of PCT International Search and Preliminary Guidelines and practices of international search and preliminary examination.

➤ OJT by supervising examiners

An officer recruited by the JPO is trained to execute examination as an assistant examiner for basically four years under the guidance of the supervising examiner.

➤ Technical training, Visits to businesses, Internship, Studying in domestic universities and overseas universities

In order to acquire the knowledge of cutting edge high level technologies, examiners are given opportunities such as attending technological trainings, visiting to businesses, internship and studying in domestic universities and overseas universities.

➤ Language training

Opportunities to receive training in English and other foreign languages are also given according to need.

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)

According to the forecast for workload prepared by office work and management division, maintenance and improvement plans for necessary resources are established to deal with demand and to comply with quality standards.

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)

Upon receipt of a PCT application, an administration schedule sheet is formed in order to keep to the schedule for preparation of the ISR and IPER for each application. This schedule, in consideration of the time limit stipulated in the PCT and the period required for procedure in the JPO, contains timing required to keep every time limit (time limit for establishing invitation to pay additional fees, notification of decision on protest, ISR, IPER etc.) in a sheet of paper, and it is distributed to examiners along with a PCT application to contribute to schedule management.

An electronic management system for PCT applications has been established and schedule management can electronically be carried out.

Directors carry out term control for PCT applications in each art unit, using these schedule sheet and electronic management system.

(b)

➤ Short-term fluctuations in demand and backlog

In order not to impartially assign a great many jobs to particular examiners and not to delay the procedure, multiple numbers of examiners in charge are assigned in the same classification. Also, a director can adjust the service volume for each examiner in charge as necessary.

➤ Medium-to long-term fluctuations in demand and backlog

Medium-to long-term fluctuations are dealt with appropriately by means of changes in examiners' assuming technical fields or transfer, etc.

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)(b)

The quality of international search and international preliminary examination work has been maintained and enhanced by checks carried out on all cases by a director or a person delegated by the director, and through consultations conducted with other examiners.

In addition, staff doing back-office work check to see whether there are any defects in terms of formalities in bibliographic items in the International Search Reports and International Preliminary Examination Reports that have been prepared by examiners, before sending them to the International Bureau or applicants.

Furthermore, the QMO takes random samples of cases that have been sent to applicants and these cases are reviewed by third-parties in the JPO to check whether the cases comply with the International Search and International Preliminary Examination Guidelines. The results of the analyses based on this internal review, in addition to user reviews and related statistical information, are presented to MDCDG, and the sections concerned should take them into consideration in forging plans to improve examination quality. These results are provided to the Art Units (See 21.06, 21.09).

(c)

When non-conformities are detected in the search and examination results, the details are provided to the sections concerned. Subsequently, these sections investigate the nonconformities and implement a plan for taking corrective and preventive actions. After a management review is conducted by MDCDG, the improvement plan is advised to and implemented by each art unit and examiner. QMO performs ongoing evaluations on the effectiveness of the improvement plan.

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.*

(As of October 31, 2010)

➤ International Affairs Division

Kenji Shimada (Mr) (Deputy Director)

Norie Umemura (Ms)

➤ Administrative Affairs Division, Examination Standards Office (Specially on (a))

Reeko Imamura (Ms) (Director)

Tomoya Yanagisawa (Mr) (Deputy Director)

Isseki Shimomura (Mr) (Assistant Director)

➤ Administrative Affairs Division, Quality Management Office (Specially on (b) & (c))

Nari Nakashima (Mr) (Director)

Kotaro Hisajima (Mr) (Deputy Director)

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)

The name and phone number of an examiner in charge are listed in the international search report and the international preliminary examination report drafted by the examiner. By this, the means for bilateral communications between applicants and examiners is provided.

In addition, QMO receives comments about examination from users. These comments are utilized for the improvement of the QMS.

(ii)

Corrective and preventive actions are taken where appropriate.

(iii)

The JPO offers comprehensive feedback to the users at the meetings described in (b) below.

(b)

QMO has been carrying out questionnaire survey to monitor user satisfaction and perception.

In addition, in order to grasp users' needs, the JPO holds periodical meetings with the associations of applicants and patent attorneys. Moreover, in order to hear direct opinions and requirements from major applicants, the JPO has been holding meetings with business executives, managers of intellectual property department and the Commissioner, the Deputy Commissioner, Director-Generals, directors, general administration sections.

(c)

The information on PCT international application is collectively described at one place to make it easy for reference (http://www.jpo.go.jp/index/kokusai_shutugan.html). This

webpage includes information about not only the PCT Guidelines, the PCT (Treaty) and PCT Regulations but also application procedures.

In addition, user's guides on international search and preliminary examination are published annually, and related workshops are held throughout Japan. These guides can be obtained through the above web site.

(d)

The JPO's quality objectives are not publicly available for the users.

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

Communications with WIPO, designated and elected Offices on quality, shall be assumed by the International Affairs Division, the Examination Standards Office, and QMO (See 21.17).

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)

The documents that make up the Quality Manual are prepared as described in 21.12(b). These documents, however, have not been composed systematically as a Quality Manual yet.

(b)

All documents can be obtained through the intranet. Part of them is provided in the form of paper media as pointed out in 21.12(b).

(c)

The documents of the latest version are always available through the intranet.

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.

The Quality Manual includes the following matters.

(a)

The "JPO's Vision" as a mission to be performed by the JPO is prepared. The quality policy of Patent Examination Departments, however, has not been developed yet.

(b)

The scope of the QMS is described on the QMO's homepage on the intranet, introducing as work products established at the international search and international preliminary examination stages.

(c)

The organizational structure of the JPO is described on the QMO's homepage on the intranet. (See 21.04 (c))

(d)

The instructions of processes carried out in the JPO can be obtained from the Portal Site of Examination Department. Part of the instructions is provided in the form of paper media (see 21.12(b)). Information about processes for the QMS is available in the QMO's homepage on the intranet.

(e)

The information on documents utilizable for prior art search, the information on the system of search, drafting, etc., and the information on trainings can be referred to through the intranet.

(f)

The figure that illustrates the interaction between the processes and the procedures of the QMS can be referred in the QMO's homepage on the intranet. (Figure 2) (See 21.06)

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 JPO has defined which documents are to be kept and where they are to be kept for almost all documents related to the QMS, but at this point has not done so for everything yet.

(b)

A management review regarding the availability of resources, etc. is conducted at MDCDG and the results are documented and stored at the Administrative Affairs Division.

(d)(e)(h)

Random sample checks are done on PCT applications in order to determine whether they comply with the quality standards (See 21.06, 21.16). A review is done at the MDCDG and the results are documented, reported to the Examination Departments, and stored at the Administrative Affairs Division.

(f)(g)

Processes of international searches and preliminary examinations are electronically recorded in the management system. These records can be viewed online, making it possible to track and trace the process of individual work.

(i)

Actions taken to respond to non-conforming products discovered at each Art Unit are recorded in the system at the discretion of the examiner, in order to store know-how on search and examination work.

(j)(k)

When problems are found, preventative plans of action are proposed in the sections concerned. These are reviewed at MDCDG, and afterward, the decision reached under

management review to prevent recurrence is advised to members of Examination Department, compiled into a written report, and stored in the Administrative Affairs Division. (See 21.06, 21.16).

(l)

Part of the search processes is recorded in a proprietary search system developed by the JPO.

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)

When an examiner uses the search system developed by the JPO, the information (i)—(v) is automatically recorded in this system. In addition, according to manuals for internal practices, as far as the case searched with other database than that for the JPO, at least the information (i) (or that of (ii) in certain instances) is recorded in the search report.

(b)

The information on viewed documents is automatically recorded in the system when using the search system developed by the JPO.

(c)

When corresponding to (i) – (iii), that fact is all recorded in the search report.

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

As already indicated above.

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]