

PATENT COOPERATION TREATY

Common Quality Framework for
International Search and Preliminary Examination

Report Under Paragraph 21.17 of the PCT International Search and Preliminary Examination Guidelines

by: **JPO**

on: **28 December 2006**

Documents referred to in this report:

[list any documents which appended to the report for information or publicly available documents which are referred to]

Each Authority must provide information with respect to its Quality Management System (QMS) arranged under the main headings as set forth in this template. The descriptions in this template below each main heading 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.

This template is to be used for a main report under paragraph 21.17 of the PCT International Search and Preliminary Examination Guidelines. Updating reports may thereafter usually be presented in abbreviated format using template T21-18.

INTRODUCTION (PARAGRAPHS 21.01–21.02)

The Authority should provide general background information relevant to the quality management system (QMS). The following may be included, if applicable:

- *Recognised normative reference or basis for quality management system besides Chapter 21, e.g. ISO 9000.*
- *An organigram showing at least the organisational units responsible for implementation of the Authority's QMS. It could be referred to in the rest of the report, as necessary.*

In Japan, the Japan Patent Office (JPO) has been carrying out patent examinations. At the same time, the demand for better examination procedures has increased. The JPO has aimed to implement accurate examinations and appropriate protection of advanced technology, along with providing timely examination according to requests and efficient search and examination at a comparable level with other countries.

In recent years, the importance of the protection of intellectual property has been widely acknowledged in Japan. At the Intellectual Property Policy Headquarters established in 2003 and headed by the Prime Minister, various topics concerned with Intellectual Property have been discussed. In order to tackle the rapid growth of the number of requests for patent examination, the Headquarters for Expeditious and Efficient Patent Examination headed by the Minister of METI (Ministry of Economy, Trade and Industry) was established in 2005, and measures for increasing the number of examinations and obtaining the cooperation of the industrial sector were implemented.

Under these circumstances, the JPO has concentrated its efforts to realize timely and high quality examinations. Every patent office, including the JPO, which is responsible for patent examination, fully realizes that high quality examination is one of the most important factors

in this job. To this end, the JPO has taken various measures for improvement in quality and will strengthen these measures in the future.

Published in October 2006 by the Headquarters for Expeditious and Efficient Patent Examination, “Advanced Measures for Accelerating Reform toward Innovation Plan in Patent Examination” sets forth the plan by which the JPO is to implement a quality management system (by April 2007) that can be applied to all technical fields and provide examiners with feedback on the quality of an examination.

This report is prepared to inform the PCT-MIA (Meeting of International Authorities) of the measures that were taken by the JPO for practicing Quality Management System (QMS) in accordance with the PCT International Search and Preliminary Guidelines Chapter 21.

QUALITY MANAGEMENT SYSTEM (PARAGRAPHS 21.03–21.09)

Establishment and maintenance of QMS (Paragraph 21.03)

The Authority should show that it has established and is maintaining, or is establishing, a QMS which:

- (a) sets out basic requirements regarding resources, administrative procedures, feedback and communication channels required to underpin search and examination (S&E);*
- (b) incorporates a quality assurance scheme for monitoring compliance with these basic requirements and with PCT/GL/ISPE.*

The duties of the JPO as the International Searching Authority and the International Preliminary Examining Authority are mainly carried out in four Patent Examination Departments and two office work and management divisions (the International Application Division and the Administrative Affairs Division). The person with the highest authority in the JPO, as the International Searching Authority and the International Preliminary Examining Authority, is the Commissioner. The Deputy Commissioner is responsible for supervising and sorting out important matters related to techniques for various operations examinations, as well as for appeals and trials. In Japan, four Patent Examination Departments have been established according to differences in the areas of technology, while the International Application Division is provided as a special division for receiving international applications.

In the Patent Examination Departments, quality management is carried out for domestic patent applications, and a similar quality management system is applied to international search and international preliminary examination under PCT. This is outlined below:

The MDCDG (Meeting of Deputy Commissioner and Director Generals) is arranged, with participants including the Deputy Commissioner as Chairman along with the General Directors from four departments. Reviews of quality, guidelines, etc. relating to the International Searching Authority and the International Preliminary Examining Authority are discussed in the MDCDG. One of the office and management divisions serves as a secretariat for the Deputy Commissioner, the MDCDG and four committees (see Figure 1).

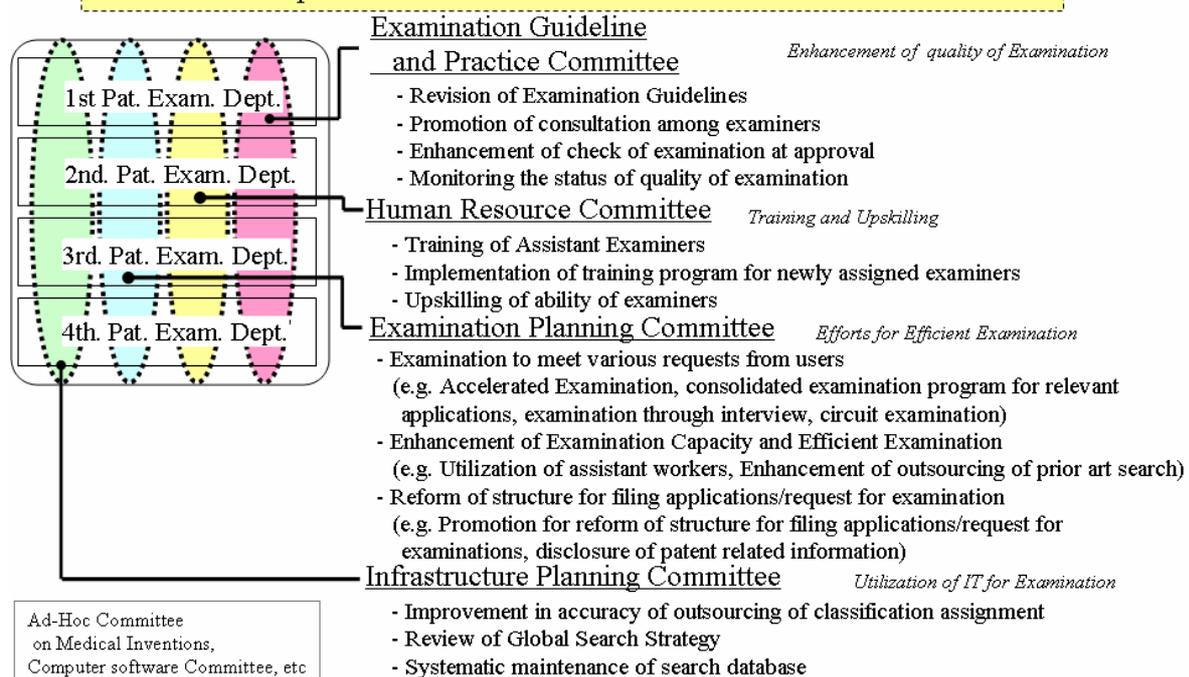
In the four Patent Examination Departments of the JPO, the management varies depending on the characteristics of each technical field. Each Patent Examination Department is composed of about twenty art units, and a director is assigned to each unit.

An art unit is the minimum management unit. Each Patent Examination Department carries out a review based on the report from a director, and files its report to the MDCDG.

Four standing committees are set up to support the management from a cross-sectional approach in the technical fields. They are: the Examination Guideline and Practice Committee, the Examination Planning Committee, the Infrastructure Planning Committee, and the Human Resource Committee. Each standing committee, from its cross sectional viewpoint in the technical fields, sums up the status quo and problems of the examination departments, researches departmental needs, collects the necessary data and information, and prepares policies and strategies in cooperation with the office and management divisions. The results are reported to the MDCDG (Meeting of Deputy Commissioner and Director for Generals). The specialties of each standing committee's approach are as follows: the Regulations and Guidelines Committee updates Examination Guidelines and promotes enhancement of the quality of prior art search and examination; the Examination Planning Committee carries out systematic and smooth transaction; the Infrastructure Planning Committee improves and maintains resources and infrastructures for effective and high quality search and examination; the Human Resource Committee aims at improvement of the quality of human resources. Each committee consists of five members; four of them are directors from each department, and one is a senior director who chairs the committee. An additional staff member, equivalent to an assistant director, supports each committee in the capacity of secretary. Those directors are all examiners.

Activity of Cross-Sectional Committees

Cross-sectional organization to discuss issues which are shared among examination departments



The Infrastructure Planning Working Group is established as a subordinate organization of the Infrastructure Planning Committee, and functions as a cross-sectional organization in technical fields. The Infrastructure Planning Working Group consists of representatives from each art unit. The Infrastructure Planning Working Group informs each examiner of information regarding computer hardware and software to be used as examination tools, and also collects up and discusses the requirements from each examiner.

In this age, when technology is progressing rapidly, specialized investigation in technical field, in a particular in the most advanced technology, is required in some cases.

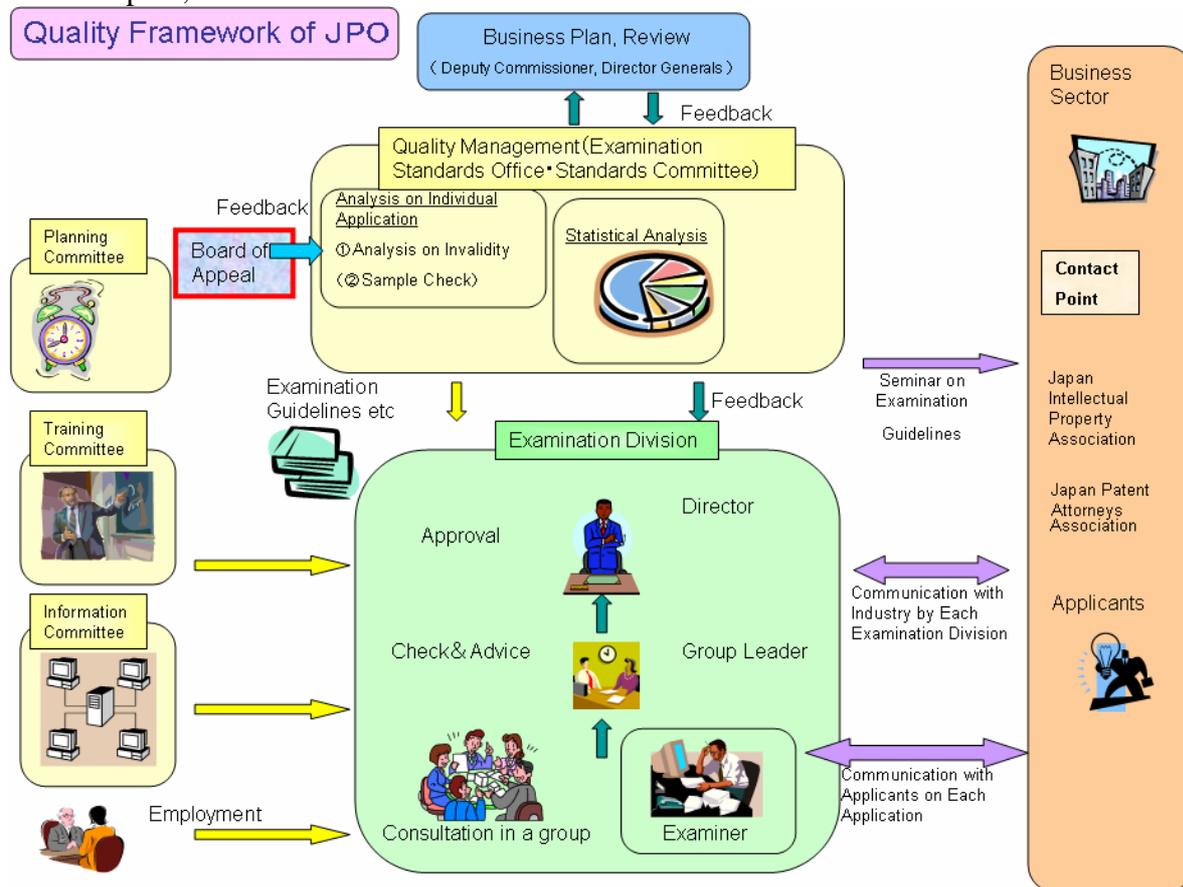
Since it may become necessary to intensively discuss the matters specific to a particular technical field, the Computer Software Committee, the Biotechnology Committee and the Ad-

Hoc Committee on Medical Inventions have also been established and each committee consists of examiners who are specialized in each technical field.

The MDCDG reviews the whole operation of Patent Examination Departments twice a year, based on the reports from each department, each committee and the office management divisions. At a year-end review, evaluation of the fiscal year is made and policy for the next fiscal year is decided. The contents of the review are reported to patent examiners in each Patent Examination Department. Moreover, this review information is made available for reference and utilization at any time through the electronic bulletin board. Thus macroscopic feedback of the reviews is provided.

A Classification and Schedule Managing Officer for each patent examination department and one manager for technical information (PCT schedule managers) for each art unit are assigned respectively. Such persons in charge, together with a director of each art unit, carry out their duties to ensure each case proceeds smoothly.

The Figure 2 covers various factors in connection with examiners and examinations. As shown in this Figure, the examiners strive to make high quality examinations still further by consulting with other examiners, make a drafting as a result of international search and/or preliminary examination. The draft will be checked by the group leader, the manager for technical information, and an approver equivalent to Director. In a series of this checking process, such instructions as advice and feedbacks are adopted. As a function to support sections to carry out such actual examinations, trainings, examination standards, IT system, adjustment of duty volumes surround examiners. The examiners also communicate with outside users and applicants. A series of these policies are collected as a business plan, and then reviewed and reformed in MDCDG.



Provide information about the infrastructure in place which ensures the following:

- (a) Adequate quantity of search and examination (S&E) staff, including:
 - (i) means for matching the quantity of S&E staff to the inflow of work;*
 - (ii) means for ensuring that recruited S&E staff have the necessary technical qualifications;*
 - (iii) means for ensuring that S&E staff have language skills, or have access to supporting translation arrangements, as necessary to meet Rule 34.**
- (b) Adequate quantity and skills of administrative staff to support S&E.*
- (c) Provision of appropriate equipment and facilities to support S&E.*
- (d) Provision of the minimum documentation supporting S&E, as referred to in Rule 34.*
- (e) Provision of up-to-date work manuals. These must include explanations of:
 - (i) quality criteria and standards;*
 - (ii) descriptions of work procedures;*
 - (iii) instructions ensuring that the work procedures are adhered to.**
- (f) Provision of an effective training and development program for all staff involved in S&E, including means to ensure the acquisition and maintenance of the necessary experience, skills and familiarity with work manuals.*
- (g) Continuously monitoring and identifying resources, other than staff, required to deal with demand and comply with quality standards for S&E.*

(a) In the JPO, Patent Examiners carry out search and examination. The JPO has 1,468 examiners (in FY2004) who generally have a technical educational background from universities or colleges, and at least a bachelor's or a master's degree. Some of them have a doctoral degree. The JPO recruits examiners from applicants who passed the first Level national public servant recruitment examination, in the divisions of science and engineering or agriculture. The relevant 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 Level national public servant recruitment examination. The JPO regards English ability as an essential element in recruitment of its staff. Assistant examiners are required to receive specified English language training before they are promoted to examiners. They can also participate in training courses in other foreign languages such as French, German, Russian, Chinese, etc.

As a provisional measure to cope with further increasing backlogs, the JPO formulated a plan to employ highly specialized outside human resources as fixed-term examiners at the rate of about 100 persons per year for five years, about 500 in total. For each 2004, the initial year, 2005 and 2006, the JPO increased 98 fixed-term examiners. The JPO gives an examination, equivalent to Class 1 Examination for Government Employees, to strictly evaluate their nature, and employed them.

(b) In order to implement search and examination smoothly, about 40 members of the International Application Division, in charge of office management, support examiners. Before those staff members begin to work at the International Application Division, they receive appropriate training relating to the whole PCT system, search and examination processes and work contents. When the PCT rules are revised, they will have an opportunity from time to time to attend a training course to keep pace with the revised rules.

Systematic measures are taken to support these staff members. A computer is available for each person, and they have access to computerized information concerning international applications under PCT.

(c) 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, and are extremely important for examiners to execute international search and international preliminary examination. They replace the old ones periodically, and are upgraded upon request from the examiners 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 JOIS and which can be executed by a single PC terminal.

Access to Japanese and foreign patent documents, as well as NPL (Non Patent Literature), is possible from this search terminal. For retrieval of foreign patent documents, search using ECLA/US classifications is possible.

There are many original search systems developed by the JPO. They include: the F-term system 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 selected from appropriate multiple viewpoints are assigned. Persons with profound knowledge of both technology and patents have previously analyzed the technical documents and have assigned an appropriate "terms" to each technical group. Therefore, with the F-term system a more precise search is available than searches by using key words, etc. In addition, with the F-term system and FI system, IPC and search using key words can be simultaneously made so that a quick and extremely precise search is executed. With respect to NPL (Non Patent Literature) about computer software, the JPO has developed its own database of computer software.

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, important documents and related documents found in a search formula or during a search can be saved, and search know-how can be shared among examiners.

When an examiner establishes International Search Reports or International Preliminary Examination Reports, report preparation support by macro functions has been realized.

Especially, innovations to prevent drafting mistakes are provided, such as mounting of functions to permit simultaneous drafting of important documents, a function of automatic import of bibliographic matters to drafting documents, a checking functions for input contents, etc. Moreover, in 2005, electronic management and electronic approval procedure for PCT applications will be realized, and still further enhancement of an IT system to support examiners is scheduled.

The office management divisions, along with the Infrastructure Planning Committee, jointly analyze the functions and the performance of the information systems and make a review of the systems every year. The systems are reviewed every year and measures for their improvement are designed to meet the requirements from examiners, in order to provide comfortable environments where the examiners can execute the highest quality searches and preliminary examinations with maximum efficiency.

(d) The JPO possesses a substantial amount of documentation, mainly comprising patent documents for the purpose of executing international search and international preliminary examination. With respect to patent documents, the National Center for Industrial Property Information and Training possesses all official gazettes corresponding to minimum documents, and the JPO examiners are able to utilize these gazettes. In addition, for most part of the official gazettes of the minimum documents, examiners are free to access those documents from their search terminals. For the non-patent literature, the JPO is able to utilize

commercial on-line databases including Science Direct, INSPEC and JOIS possessed by the National Center for Industrial Property Information and Training, thus, it secures to access a wide range of non-patent literatures, making it possible to meet the requirements for minimum documentation.

(e) The “PCT Handbook” is a basic practice manual compiled by the JPO for examiners carrying out international searches and preliminary examinations, and each examiner is given a hard copy. The PCT handbook contains comprehensively written descriptions, covering topics ranging from criterion of judgment for international searches and preliminary examinations to procedures of the internal system. It is based on rules and regulations such as the Treaty, the Regulations and the PCT International Search and Preliminary Guidelines and the operational procedure of the internal system (PCT-RO).

Additionally, another handbook titled “Guidance for How to Draw Up a PCT International Search Report”, which provides case examples, has been compiled and distributed to support the work of each examiner. The relevant information, including the PCT Handbook and the PCT Guidelines, is publicized on the JPO intranet and electronically available at any time for utilization. The above-mentioned publications are revised from time to time according to a change of rules and of operational procedures, and the points of such a change or revision is summarized and delivered to each examiner immediately.

On the topic of classification, manuals that describe practically relevant points to note are available for perusal via each examiner’s PC terminal.

Furthermore, a strategic search file that summarizes know-how for search is available to all examiners through the intranet immediately after completion.

With regard to terminal operating instructions and the content and operational directions of various databases, manuals are compiled and are available to all examiners through the intranet.

In addition, while the International Application Division has so far carried out administrative work for PCT-related international search and preliminary examinations according to manuals that are constantly updated based on each business. Taking a step further from 2004 to 2005, so-called “Manuals for Administration and Operation Procedure”, that have comprehensively integrated managerial operations, have been prepared. Accomplishing the operations based on the manuals will actualize the technique to maintain the operational level of the staff of the International Application Division. The staff in the said division meets regularly as the committee in order to cope with any problems in business, and inform the updated manuals their familiarization.

At the same time, there is also “FAQ on PCT Procedures” which formalizes procedures addressing special cases of international application under PCT, including Q & A.

Incidentally, the relevant Q&A, “FAQ on PCT Procedures” is disclosed on the JPO official web site (<http://www.jpo.go.jp/tetuzuki/index.htm>), and information is provided not only for the staff at the International Application Division but also for PCT users.

(f) The JPO has the National Center for Industrial Property Information and Training (NCIPI) as an institute to comprehensively assume the JPO’s Trainings. This Information and Training Center plans training programs multilaterally including laws and technologies, and executes them. The JPO and the NCIPI communicate closely with each other, and upon planning and execution of the training program, the Human Resource Committee, a cross-sectional organization in technological fields, works in cooperation with the NCIPI.

Lecturers for this training program include university professors, lawyers and examiners. Under each department there are additional groups of about ten supervising instructors mainly including associate managing examiner level staff (deputy director of each art unit). Each group of instructors executes original training program in addition to that provided by NCIPI for each group of assistant examiners in the first year.

An officer recruited by the JPO is trained to execute examination as an assistant examiner for four years basically under the guidance of the instructor. During this time the assistant examiner must attend at least three training courses and pass the examination for each course. The total hours for the three training programs are around 250 hours.

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 internship with international search and preliminary examination. An examiner is given an opportunity to extend his or her knowledge of technology as the need arises, in order to learn the most advanced technology that is used in R & D of private enterprises. To be more precise, opportunities include studying in both domestic and overseas universities, attendance at various academic conferences, internship programs at private enterprises to learn technology actually used in the industry, participation in various technical sessions and field trips to observe production lines and products on-site at enterprises and R&D facilities. In addition, technical training at special courses is organized by way of inviting lecturers to the JPO, both as the need arises and at the request of each art unit. Opportunities to receive training in English and other foreign languages are also given according to need. By enhancing technical knowledge and communication skills in a foreign language, the examiner is better able to understand an invention filed and to carry out international search and international preliminary examination duties. The office management divisions and the Human Resource Committee jointly analyze and review the system of training programs and recruiting human resources annually. And the system is reviewed every year so as to meet requirements and to achieve maximum effect.

(g) There are about 20 art units (divisions) in each examination department in the JPO and there is one technical information manager (PCT schedule manager) in each art unit. Managers for technical information (PCT schedule manager) are assigned various tasks: checking up the documents prepared by an examiner; assignment of each examiner in each art unit; adjustment of work volume; management of the progress status of International Search Report and International Preliminary Examination Report; and review of classification. Particularly, in regard to documents produced by an examiner, Manager for Technical Information (PCT schedule manager) checks them prior to the final approval made by executive officers and supplies feedback to each examiner according to need. Moreover, directors check the documents drafted by each examiner, give feedback to examiners if needed, and make final approval if there is no problem. Staff in the International Application Division checks whether there are errors in bibliographic and formality items in the International Search Report and International Preliminary Examination Report prepared by examiners before sending them to International Bureau. These staff members are trained and managed appropriately by the executive officers of the International Application Division to enhance the quality of search and preliminary examination.

Administration - procedures (Paragraphs 21.06(a) and (b))

Provide information on those administrative procedures and control mechanisms which ensure the following:

- (a) *Timeliness of S&E and related functions, to quality standards in accordance with PCT/GL/ISPE.*
- (b) *Coping with fluctuations in demand and backlog management.*

(a) Upon receipt of an international patent application, an administration schedule 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 Agreement and the

period required for procedure in the JPO, contains timing required to keep every time limit (time limit for establishing the notification about lack of unity of invention, 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 managements. The JPO gives top priority to the timely execution of search and examination of an application addressing PCT. There is a Classification and Schedule Managing Officer assigned in each of four departments.

The Classification and Schedule Managing Officer is responsible for the application jointly with a manager for technical information (PCT schedule manager) until the examiner in charge is duly assigned.

The assignment of classification and the assignment of an examiner are made within four days after distribution of documents. In a case where an examiner is not assigned within four days, the manager for technical information (PCT schedule manager) should demand a duty officer's meeting or an administration managers' meeting and should confirm that the meeting takes place. After debate at the meeting, if the assignment of the examiner in charge is still not decided, Director of Classification Planning can decide the main technical field. After the assignment of the examiner, the manager for technical information (PCT schedule manager) supervises the administration schedule in order to prepare the draft in time. With these procedures put in practice, the JPO prepared ISR and IPER within the time limit stipulated in the Treaty, the Regulations, and the Guidelines at a quite high level of achievement.

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

Quality Assurance Procedures (Paragraph 21.07)

Provide information on procedures which ensure that S&E reports of a quality standard in accordance with PCT/GL/ISPE are issued. In particular, provide information on:

(a) Activities related to verification, validation and monitoring; as carried out in order to assess compliance of S&E work with PCT/GL/ISPE.

(b) Processes for measuring, recording, monitoring and analysing performance of the QMS to assess its conformity with the requirements of Chapter 21 and, if applicable, any other normative reference for the QMS.

(c) Activities related to verifying the effectiveness of actions taken to deal with deficiencies, including:

(i) those actions taken to eliminate, correct or authorise release of deficient S&E work which does not comply with the quality standards;

(ii) those actions taken to eliminate the causes of deficient S&E work and prevent the deficiencies from recurring.

(d) Activities ensuring the continuous improvement of established processes underpinning the issue of S&E reports.

(a) In respect to Quality Control, the most important thing in the JPO is the process itself of the international search and international preliminary examination to establish more appropriate ISR/IPER. Therefore, a director, a manager for technical information (PCT schedule manager) and a group manager review, with multiple pair of eyes, all the contents of international search and international preliminary examination. Therefore four members, including an examiner in charge, check the contents in order to ensure quality.

In particular, a check made at the director level is not only to examine the contents of application documents, but is frequently also to advise an examiner in charge and give guidance in order to ensure quality on each case. Almost all directors have experience

engaging in the Appeals Department as an appeal examiner for upper instance. Also, the examiner can ask for cooperation or technical advice from other examiners. In particular, each art unit is divided into several groups and a group leader is assigned to each unit.

The group leader proactively advises examiners in order to execute a thorough search and preliminary examination. Furthermore, there are specialists in each office and administration department who check for clerical mistakes, such as errors and omissions in writing.

(b) The JPO will strengthen its quality management system by requiring that the office actions approved by directors are inspected by other the JPO officials. The JPO is conducting a pilot project of this “multiple inspection” system with PCT ISRs/IPERs.

After thorough analysis of the results of this pilot project, the JPO will establish a cross-sectional quality management system on a step-by-step basis from the spring of 2007.

(c)(d) For overall problems, office and administration division and the Examination Guideline and Practice Committee jointly analyze them, and such problems are reviewed annually by the MDCDG, as the need arises. When necessary, measures are taken immediately. The results of the review are distributed in writing to each department concerned and are also posted on the intranet web site.

Feedback arrangements (Paragraph 21.08)

Give information on arrangements to:

(a) Provide feedback to staff informing them of results of verification, validation and monitoring carried out in order to assess compliance of S&E work, so that:

(i) deficient S&E work is corrected;

(ii) corrective action, i.e. action necessary to prevent recurrence, is identified and implemented;

(ii) best practice is identified, disseminated and adopted.

(b) Accommodate prompt feedback from WIPO, designated and elected offices; so that potential systemic issues, e.g. recurring deficiencies of S&E work, as identified by these bodies, are evaluated and addressed.

(a) In order to improve performance, frequent intra-office reviews are held as described after. The results of the intra-office reviews are fed back to each examiner through the multifaceted process consisting of the MDCDG (Meeting of Deputy commissioner and Director General), various kinds of committees including the Examination Guideline and Practice Committee, and each examination section. In addition, the countermeasures of each section noted in the review and the accumulated know-how are utilized as common assets among all examiners through a feedback process.

They contribute to popularization of the best practices.

(b) As a communication channel to the WIPO and the designated offices (the elected offices), the International Application Division is responsible for the institutional aspect of PCT and the potential institutional problems. The JPO holds regular sessions, particularly with the WIPO, on business matters and also assigns the Administrative Coordinator for PCT Affairs in order to deal with institutional problems. In 2005, the JPO established “International Application Administrative Affairs Office in International Application Division which is responsible for international adjustment of institutional problems, and also assigned international application experts in the office in order that the International Application Administrative Division takes charge of challenging to institutional issues continuously and unitarily. The Office is expected to effectively analyze and discuss the problem to reinforce the system.

Moreover, in the “Guidance for the Applicant to PCT” posted on the WIPO PCT home page,

the international application division of the JPO is introduced as the office in charge of the PCT international patent application.

Communication, Guidance and Responses to Users (Paragraphs 21.06(c), 21.09)

Give information on arrangements to:

- (a) Provide communication channels for dealing promptly with enquiries and enabling appropriate two-way communication between applicants and examiners.*
- (b) Provide concise and comprehensive guidance and information to users (particularly unrepresented applicants) on the S&E process using the website of your Authority, guidance literature, and other means.*
- (c) Monitor and react to user needs and feedback, including:
 - (i) measuring user satisfaction and perception;*
 - (ii) handling complaints;*
 - (iii) correcting deficiencies identified by users;*
 - (iv) taking corrective action, i.e. action to eliminate the cause of deficiencies, in response to recurring or systematic deficiencies identified by users.*
 - (v) taking preventive action, i.e. action to eliminate the cause of potential deficiencies, in response to potential deficiencies or problems identified by users;*
 - (vi) ensuring needs and legitimate expectations of users are met.**

(a) Bilateral communication between applicants and examiners

The name and phone number of a JPO examiner are listed in the international search report and the international preliminary examination report drafted by the examiner, and the examiner's phone number and division are also accessible through the JPO website. Through these measures, the means for bilateral communication between applicants and examiners is provided.

The International Application Division handles any general inquiries and procedures concerned with search, examination, and international applications. Moreover, when receiving a substantive inquiry regarding a search, examination, or international application, the International Application Division contacts the appropriate persons, including the examiner concerned. In this manner, the division provides for contact between an examiner and an applicant.

(b) Guidance to users

A Japanese language version of the PCT International Search and Preliminary Guidelines is posted on the JPO website. Posting a Japanese language version of the PCT Handbook on the JPO website is also under consideration. An information desk has been created to handle all inquiries, including those concerned with PCT Guidelines, the PCT (Treaty), and PCT Regulations.

In addition, a user's guide on international search and preliminary examination is published annually, and related workshops are held throughout Japan.

(c) In the International Application Division, which accepts international patent applications, the Administrative Affairs Section of the Division takes complaints from outside of the office, and informs the appropriate office (such as the Administrative Affairs Division and Examination Standards Office) of the complaints and then deals with the complaints and works to alleviate problems together with the examiner.

Also, it is clearly stated in the JPO official web site that the International Application Division deals with the complaints from outside, takes advice from outside and is mentioned as a

reference. Once a complaint is received, the administration offices promptly take countermeasures against it. Necessary measures are immediately taken, and this is publicized in the Intranet web site, and is also distributed to the offices concerned in written form. In addition, the JPO holds a regular session with the association of patent attorneys. The Commissioner, together with the Deputy Commissioner, office managers, directors and administration divisions, hold a session from time to time with executives and persons in charge of intellectual property at private enterprises in order to directly hear requests from applicants. Minutes of each session is reported to administration divisions, various committees and each office manager and used as an appropriate reference when various reviews are made. At the same time, the International Application Division and the Examination Standards Office hold a regular briefing session for users, and explore appropriate countermeasures reflecting users' satisfaction and opinions obtained.

The JPO is conducting a pilot project of this assessing the level of users' satisfaction by means of a survey questionnaire on each ISRs/IPERs distributed to applicants with PCT applications this year.

INTERNAL REVIEW (PARAGRAPHS 21.10–21.15)

Paragraph 21.10 specifies that, in addition to a "quality assurance system for checking and ensuring compliance with the requirements set out in its QMS" [c.f. Paragraphs 21.03, 21.07], "each Authority should establish its own internal review arrangements to determine the extent to which it has established a QMS based on the above model". This model is set out by Chapter 21 as a whole [c.f. Paragraph 21.02]. Since a QMS which does not contain this provision for internal review would not meet the requirements of Chapter 21, the report under 21.17 should contain at least the information on the extent to which arrangements for internal review required by 21.10 are in place. These are as below.

Required Arrangements for Internal Review (Paragraph 21.10)

The Authority should show that arrangements are in place to ensure that:

- (a) An internal review is carried out to determine:
 - (i) the extent to which a QMS complying with the model of Chapter 21 has been established;*
 - (ii) the extent to which the Authority complies with the requirements of its QMS;*
 - (iii) the extent to which the Authority complies with PCT/GL/ISPE.**
- (b) The internal review demonstrates whether or not the requirements of the QMS and PCT/GL/ISPE are being applied consistently and effectively.*
- (c) The internal review takes place at least once a year.*

An internal review is a cross-sectional procedure to cover technical issues and is held every six months by the various committees, such as the Examination Guideline and Practice Committee. In practice, each committee receives reports from each section corresponding to the various technical areas and reviews them. Various kinds of information on the QMS system are put under review and analyzed, and measures for improvement are examined as needed.

The results of the review is also included at the MDCDG (Meeting of Deputy Commissioner and Director Generals), consisting of the Deputy Commissioner and Director Generals of each department, and then a final review is made to prepare appropriate measures and to execute them.

OPTIONAL INFORMATION UNDER PARAGRAPH 21.17

Guide to Internal Review Arrangements (Paragraphs 21.11–21.15)

Paragraph 21.11 states that 21.12 - 21.15 are “proposed as a guide to the basic components of an internal review mechanism and reporting system”, and are thus optional. Authorities may respond to the following points to indicate the provisions they have in place for Internal Review.

The Authority may show that the following arrangements are in place and will be used for the purpose of internal review:

(a) Arrangements providing information on conformity of S&E work; i.e. information from activities related to verification, validation and monitoring, as carried out in order to assess compliance of S&E work with PCT/GL/ISPE [c.f. point (a) under “Quality Assurance” above].

(b) Arrangements providing information on the effectiveness, and the extent of implementation, of the QMS and its processes; whereby it can be established to which extent the QMS complies with the requirements of Chapter 21 and, if applicable, any other normative reference for the QMS.

[End of report]