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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 organizational chart showing all those bodies and individuals responsible for the QMS.

(a)

The JPO released its “Quality Management Manual for Patent Examination”, uploading it on the JPO’s website in April, 2014.

(b)

The Deputy Commissioner is in charge of supervising and organizing important matters related to technologies, from among various operating procedures such as examinations, appeals and trials; and has responsibility for the QMS, working in coordination with the Commissioner.

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(c)

The organisational chart of the JPO is shown in Figure 1.

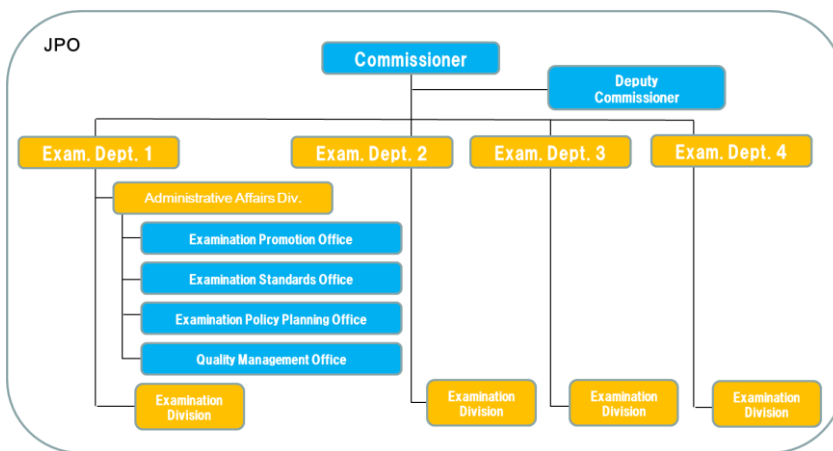


Figure 1 Organisational chart

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)	Organizational chart available	✓		
21.05		Established compatibility of QMS with Chapter 21	✓		
21.06	(a)	Mechanisms to ensure effectiveness of the QMS	✓		
	(b)	Control of the continual improvement process	✓		
21.07	(a)	Communication of management about this standard to staff	✓		
	(b)	The PCT Guidelines are in line with the Authority's QMS	✓		
21.08	(a)	Management reviews take place	✓		
	(b)	Quality objectives are reviewed	✓		
	(c)	Communication of quality objectives throughout the Authority	✓		
21.09	(a)	Performance of a yearly internal review of the QMS in/to	✓		
	(b)	determine the extent to which the QMS in based on Chapter 21	✓		
		determine the extent to which S&E complies with PCT Guidelines	✓		
	(c)	an objective and transparent way	✓		
	(d)	using input incl. information according paragraph 21.24	✓		
	(e)	recording the results	✓		
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	✓		

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

Chapter 21 requirement			Extent of compliance		
			full	part	no
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	✓		
	(c)	Document control measures are taken	✓		
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	✓		
	(iii)	Records about training, skills and experience of staff	✓		
	(iv)	Evidence of conformity of processes	✓		
	(v)	Results of reviews of requirements relating to products	✓		
	(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	✓		
	(ix)	Records on actions taken re. non-conforming products	✓		
	(x)	Records on actions taken re. corrective actions	✓		
	(xi)	Records on actions taken re. preventive actions	✓		
	(xii)	Records referring to search process documentation	✓		
21.21	(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	✓		

Chapter 21 requirement			Extent of compliance			
			full	part	no	
	(vii)		Records about limitation of search and its justification	✓		
	(viii)		Records about lack of clarity of the claims	✓		
	(ix)		Records about lack of unity	✓		
21.22			Report on its own internal review processes	✓		
21.23-21.25			Additional information on further inputs to its internal reviews	✓		
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 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 on PCT applications. These activities on quality are planned in the sections concerned. The Deputy Commissioner discusses their reasonability with the Director-Generals of the first through fourth Patent Examination Departments and Appeals Department, who are the senior officers in charge of their respective departments. Then the Deputy Commissioner decides which activities need to be worked on.

The Administrative Affairs Division is responsible for coordinating administrative affairs concerning patent examination, including planning initiatives pertaining to patent examination.

The Quality Management Office (QMO), which was established within the Administrative Affairs Division, takes responsibility for administrative affairs involved with managing the quality of patent examination. Specifically, for example, the QMO plans measures for sustaining and enhancing the quality of patent examination, which are to be implemented by the examination departments and examination divisions. These measures include consultations, quality checks (approvals), and using information on appeals. Additional measures are implemented in order to gain an understanding of the examination quality. These measures, for example, are quality audits and an annual user satisfaction survey. Moreover, the QMO provides support to analyses and evaluations on patent examination quality, which the Quality Management Internal Committee (described below) conducts by collecting various data on the quality of patent examination, for example.

The Quality Management Internal Committee, consisting of experts (directors, et al.) within the examination department, manages quality through analysing and evaluating the quality of patent examination. The Committee analyses and evaluates data that has been collected on patent examination quality such as quality audit results, appeals information, and user satisfaction survey results, in order to grasp the current state of the quality of patent examination and learn about issues to be solved, based on the standpoint of third parties, at all the examination departments and

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examination divisions. The Committee reports the results to the Deputy Commissioner and the Administrative Affairs Division, and gives feedback on data and analysis results of quality audits to the examination departments and examination divisions. The feedback, for example, could be about the results of checking patent examination quality at the time [quality checks \(approvals\)](#) are made. In addition, the Committee gives advice on various initiatives planned by the [QMO](#).

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A Committee consisting of external experts checks whether the Quality Management System outlined in the Quality Manual functions properly, in order to maintain and improve the quality of patent examination from the standpoint of third parties. Furthermore, the committee objectively evaluates the current state and system of quality management. The external experts who are on the Committee have expertise in managing quality and/or have academic backgrounds and relevant knowledge. The results of the evaluations conducted by the Committee are taken into consideration when initiatives on patent examination procedures are modified and when patent examination policies are planned, so as to maintain and improve the effectiveness of the Quality Management System.

The Deputy Commissioner reviews the QMS for patent examination based on the results received from the Quality Management Committee as well as on other information received (See 21.09) with the Director-Generals of the first through fourth Patent Examination Departments and Appeals Department, who are the senior officers in charge of their respective departments. The Deputy Commissioner makes decisions on measures and actions that need to be implemented, based on the results of quality management reviews, in order to ensure that the QMS is effective and continuously improved.

The JPO ensures that the QMS is effective and continuously improved, based on the organization and the mechanism described above.

For example, in order to maintain and improve the quality of patent examination work, examiners consult with other examiner(s) and share their expertise on search strategies, etc. In addition, directors and the like conduct quality checks (approvals). Based on these activities, the JPO strives to ensure that proper examinations on each individual case are achieved, in order to standardise examiners' practices.

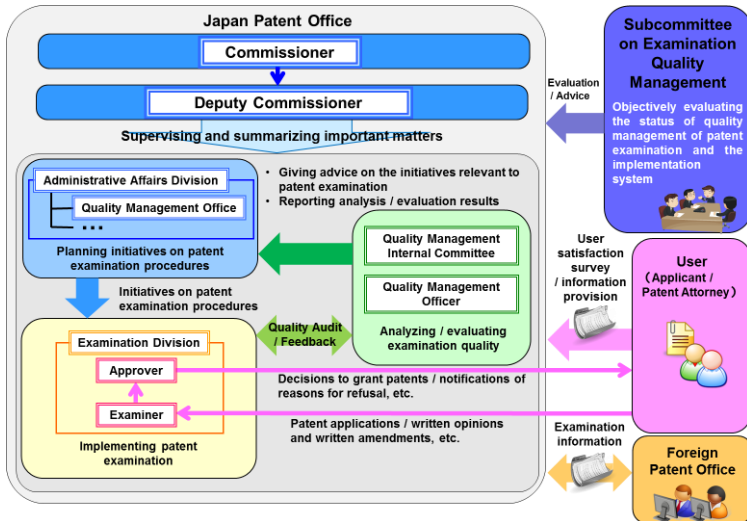


Figure 2 Outline of the QMS

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

- (a) those of this standard; and
- (b) complying with the Authority's QMS.

(a)(b)

The JPO communicates to its staff, including examiners, the importance of meeting quality standards and complying 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, with the Director-Generals of the first through fourth Patent Examination Departments and Appeals Department, who are the senior officials in charge of their respective departments, shares information and conducts management reviews on human resources, physical resources, and educational resources, if necessary, once or twice a year.

(b)(c)

At the beginning of each fiscal year, the Deputy Commissioner, with the Director-Generals of the first through fourth Patent Examination Departments and Appeals Department, who are the senior officials in charge of their respective departments, shares information and reviews/revises the handling targets of examination, including quality objectives. The handling targets of examination are notified to all examiners.

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).

(a)

The Deputy Commissioner, with the Director-Generals of the first through fourth Patent Examination Departments and Appeals Department, who are the senior officials in charge of their respective departments, shares information and conducts management reviews on the QMS once or twice a week, if necessary. In addition, a comprehensive management review of the QMS is carried out at the end of each fiscal year.

(b)(d)

The input to the management review includes:

- Results of review of sampled cases (See 21.12 (a));
- Results of consultations among examiners on PCT applications (See 21. 12 (a));
- Statistical data related to quality (See 21. 12 (b));
- Feedbacks from users (See 21. 12 (b));
- Results of analysis on discrepancies between ISRs and FAs in the National Phase (See 21. 12 (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.
- Evaluations and advice by External Expert Committee

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

Human resources:

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

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

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

is maintained and adapted to changes in workload.

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

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

for the documentation of records.

(i)

In the JPO, patent examiners carry out search and examination. These patent examiners generally have a technical educational background from universities or colleges and have at the minimum a bachelor's degree. There also are examiners with master's degrees or doctor's degrees. The JPO recruits examiners from candidates who passed the Examination for Comprehensive Service, in the divisions of engineering, chemistry, biology, pharmacy, etc. This examination is rated as the most difficult among all national public servant recruitment examinations. Furthermore, successful candidates undergo character tests that evaluate their personal nature and personalities.

English is one of the subjects in the Examination for Comprehensive Service. The JPO regards English ability as an essential element when recruiting staff. Moreover, assistant examiners have a chance to receive specified English language training before they are promoted to examiners. Examiners can also participate in training courses to learn other foreign languages such as French, German, Korean, Chinese, etc.

As a provisional measure to cope with further increasing backlogs, the JPO since FY 2004 has been hiring highly specialized, outside human resources to work as five-year, fixed-term examiners. The JPO employed fixed-term examiners from fiscal years 2014 to 2016. The JPO gives the candidates an examination that is equivalent to the Examination for Comprehensive Service. In addition, it conducts character tests and strictly evaluates their natures and personalities, finally employing the successful ones.

As of FY2016, the JPO has 1,702 examiners in total, which include 496 fixed-term examiners.

(ii)

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

Material resources:

(iii) Describe the infrastructure in place to ensure that appropriate equipment and facilities such as IT hardware and software to support the search and examination process are provided and maintained;

(iv) Describe the infrastructure in place to ensure that at least the minimum documentation referred to in Rule 34 is available, accessible, properly arranged and maintained for search and examination purposes. State whether it is on paper, in microform or stored on electronic media, and where.

(v) Describe how instructions:
to help staff understand and adhere to the quality criteria and standards; and;
to follow work procedures accurately and consistently
are documented, provided to staff, kept up-to-date and adapted where necessary.

(iii)

➤ [IT Hardware and Software that Support the Search and Examination Processes](#)

Resources include a [search system](#) for effectively executing searches of prior art documents such as minimum documentation, and a drafting system for [establishing ISRs or IPERs](#). 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.

[The JPO makes use of its proprietary search system, which enables access to domestic/foreign patent literatures and non-patent literature. Furthermore, the JPO has contracted with approximately 40 external commercial database providers in order to conduct prior art searches. Retrieval styles that have been used in searches, and a document set obtained based on the retrieval style, can automatically be recorded. This makes it possible for examiners to share their knowledge about searches with each other, which is useful in terms of quality audits.](#)

[The JPO has set up support functions that help examiners issue JSRs or IPERs, by using a drafting system. The support functions permit simultaneous drafting of necessary documents, automatically import bibliographic data to drafting documents, and check the report contents, for example. Moreover, this makes it possible to administer and approve procedures electronically for PCT applications.](#)

[A dual-display terminal is assigned to each examiner so as to facilitate screening of patent literature and non-patent literature with a larger-size display.](#)

➤ [Search Indexes for Searching Patent Literature](#)

[For efficient searching of Japanese patent literature, JPO maintains classification which is referred to as "File Index" \(FI\) and search index referred to as "F term". FI is subdivision of IPC for Japanese patent literature, F term is search index in which multiple aspects are developed for each of approximately 2,600 technical groups based on FI. JPO's examiners can combine full-text search with FI/F term in the prior art search. They can screen patent literature groups with](#)

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using FI/F term. Therefore, JPO achieves efficient and highly accurate search through them. JPO's examiners use not only IPC or full-text search but also ECLA, CPC, or USPC when searching foreign patent literature.

➤ Tools and Equipment for Non-patent Literature Search

JPOs need thorough search of both patent and non-patent literature.

Therefore the JPO stores useful non-patent literature in its internal database. The search system uniquely developed by the JPO provides seamless search between patent and non-patent literature.

The JPO improved its search environment for technical standards and draft version of technical standards submitted during the process of establishing the standards in recent years. JPO expanded the coverage of standard-related documents that can be stored in the internal database through the collaborative relationships with standards setting organizations (SSO).

➤ Search Indexes for Non-patent Literature

The JPO sets up search index referred to as "CS term" for efficient search of non-patent literature. It is similar to the above-mentioned F term. CS term is a computer software-specific search index in which multiple aspects are developed for each technical group.

Similarly to the F term used for patent literature, JPO's examiner can combine full-text search with CS term. They can screen non patent literature groups with using CS term.

(iv)

The JPO possesses a substantial amount of documentation with focus on patent literature. The JPO's examiners can utilize patent publications corresponding to minimum documentation through using internal search systems and commercial databases. For non-patent literature, the JPO's examiners can utilize documents stored in the JPO and commercial databases. Thus, it is able to access non-patent literature corresponding to minimum documentation, making it possible to meet the requirements for searches on minimum documentation as an ISA.

(v)

The Quality Management Manual for Patent Examination, i.e., the "Quality Manual", outlines procedures for and the persons in charge of quality management. Also, the Quality Manual provides documents that can be used as references in order to obtain the details of procedures and the persons in charge. Initiatives on quality management are conducted based on the Quality Manual and documents that can be used as references. The main references are as follows;

➤ "PCT International Search and Preliminary Examination Guidelines"

The Guidelines are available on the WIPO website. A Japanese translation of the Guidelines revised in October 2015 is available on the JPO's website.

➤ "Handbook for PCT International Search and Preliminary Examination in the Japan Patent Office"

The JPO created and released a new booklet called the "Handbook for PCT International Search and Preliminary Examination in the Japan Patent Office", referred to as "PCT Handbook". It is available in

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削除: ... he JPO possesses a substantial amount of documentation, ... which consists of mainly... ith focus on patent literature documents... The JPO's examiners are able to... an utilize patent publications corresponding to minimum documentation through using internal search systems and external ... ommercial databases. designed to conduct prior searches... For NPL... on-patent literature, the JPO's examin

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both Japanese and English versions as of October 2015. It gives instructions about operating procedures and judgement criteria for international searches and preliminary examinations under the PCT. Hard copies of the PCT Handbook are given to examiners. The PCT Handbook gives thorough explanations on judgement criteria when examiners conduct international searches and preliminary examinations, as well as on the JPO's own internal operating procedures, based on the Treaty (PCT), Regulations under the PCT, and "PCT International Search and Preliminary Examination Guidelines", and the JPO's own internal operating procedures (PCT-RO). The Handbook gives: (1) [overview of the PCT system](#), operating procedures for examiners who are in charge of PCT international searches and preliminary examinations, using flow charts, figures, and tables; (2) instructions on what examiners are to write in each box on PCT Forms; and (3) clear judgement criteria during the international phase, showing the relation to the "Examination Guidelines for Patent and Utility Model" which is applied to national patent applications.

➤ Computer System Operations Manuals

[The JPO has manuals explaining how to operate its computer systems, which are used by examiners. It thoroughly explains the systems. Hard copies of the manuals are distributed to each Examination Division. Examiners can view these on the intranet. In addition, the JPO provides examiners with training on how to operate the systems, using handouts based on the manuals.](#)

The JPO provides the Quality manual on its website also.

Training resources:

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

acquire and maintain the necessary experience and skills; and

are fully aware of the importance of complying with the quality criteria and standards.

(vi)

➤ Course training

An officer recruited by the JPO is required to attend two training courses and pass the examinations for each course before becoming an examiner. Total hours of two courses are 250 hours. Lecturers for this training program include university professors, patent attorneys and examiners. The training programs include training on 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

Officers recruited by the JPO are trained to conduct examinations as assistant examiners for 2-4 years, depending on their prior experience, working under the guidance of supervising examiners.

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

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In order to acquire the knowledge of cutting edge high level technologies, examiners are given opportunities such as attending technological training, visiting businesses, internships, 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.

Oversight over resources:

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

to deal with demand; and

comply with the quality standards for search and examination.

(vii)

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

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.

(i)

Upon receipt of a search copy or a demand for international preliminary examination, an administration schedule sheet is created in order to enable examiners to adhere to the set schedule required for issuing ISRs and IPERs for applications. This schedule, in consideration of the time limit stipulated in the Treaty and Regulations, as well as the period required by the JPO to complete internal procedures, outlines the timeframe needed for adhering to every time limit. These include time limits for establishing intermediate invitations, such as invitations to pay additional fees etc., notifications of decisions on protests against additional fees, ISRs, IPERs, etc. The schedule, along with an international application, is distributed to examiners in order to assist them in managing their schedules.

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 examination division, using these schedule sheet and electronic management system.

(ii)

➤ 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

21.12 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.

(i)(ii)

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, staffs doing back-office work check to see whether there are any defects in terms of formalities in bibliographic items in the JSRs and JPERs that have been prepared by examiners, before sending them to the International Bureau or applicants.

Furthermore, "quality audits" became a standard practice in FY2014 after they were conducted on a pilot basis for two years. The quality audits include additional searches as needed. The Quality Management Officers take random samples of cases before any notices are sent to applicants and review them to see if they comply with the International Search and International Preliminary Examination Guidelines. Examiners in charge are in principle given feedback on the results of Quality Audits when necessary, after the Quality Management Officers and Directors have discussed them. The results of the analyses based on this internal review, in addition to user reviews and related statistical information, are presented to the Deputy Commissioner, with the Director-Generals of the first through fourth Patent Examination Departments and Appeals Department, who are the

削除: International Search Report

削除: International Preliminary Examination Report

senior officers in charge of their respective departments, and the sections concerned should take them into consideration in forging plans to improve examination quality. These results are provided to the Examination Divisions (See 21.06, 21.09).

Moreover, on a pilot basis this fiscal year the JPO began analysing files categorized under the following cases, in which discrepancies on search and examination results between offices were found:

- PCT applications, in which only A documents were cited in the ISR/JP, while XY documents were cited at the FA by other offices at the national/regional phase

In principle, Directors give examiners in-charge feedback on the analysis results of individual files and instruct them when necessary.

(iii)

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 the management review is conducted by the Deputy Commissioner, with the Director-Generals of the first through fourth Patent Examination Departments and Appeals Department, who are the senior officers in charge of their respective departments, the improvement plan is advised to and implemented by each examination division and examiner. QMO performs ongoing evaluations on the effectiveness of the improvement plan.

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:

- helping identify and disseminate best practice among Authorities;
- fostering continual improvement; and
- 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 [November 30, 2016](#))

➤ International Policy Division, Multilateral Policy Office

[Tatsuo Takeshiqe \(Mr\) \(Director\)](#)

[Shinichiro Hara \(Mr\) \(Deputy Director\)](#)

[Marina Nasu \(Ms\) \(Administrative Official\)](#)

削除: January 5

削除: Yoshinari Oyama

削除: Chiaki Muro

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

Kiyoko Tamura (Ms) (Director)

[Yoshitaka Ota](#), (Mr) (Deputy Director)

[Shunsuke Yamamoto](#), (Mr) (Assistant Director)

削除: Tetsuya Ishihara

削除: aneki

削除: Tadashi Kitanaka

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

[Hiromi Takaoka](#), (Ms) (Director)

[Ryo Washizaki](#) (Mr) (Deputy Director)

削除: Masahiro Nishina

削除: r

削除: Hideaki Shimada

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's web site, guidance literature.

(iv) An indication of where and how the Authority makes its quality objectives publicly available for the users.

(i)

The name and phone number of an examiner in charge are listed in the [JSR](#) and the [JPER](#) drafted by the examiner. By this, the means for bilateral communications between applicants and examiners is provided.

削除: international search report

削除: international preliminary examination report

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

Corrective and preventive actions are taken where inappropriate.

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

(i)(ii)

The QMO has been carrying out a questionnaire survey to monitor user satisfaction and gain insight on their perceptions about the JPO's quality. In this fiscal year, the survey regarding the quality of work products in international phase such as JSRs targeted 732 applicants and covered 2,738 applications. Furthermore, the JPO will make a detailed analysis of the statistical data gathered from the survey and an analysis of individual applications gathered from the survey. The survey results in the past are available on the JPO's website (<http://www.jpo.go.jp/seido/hinshitsukanri/tokkyo.htm>).

In addition, in order to grasp users' needs, the JPO holds meetings with applicants, industry groups, and patent attorneys working in patent offices.

(iii)

In order to make it easier for users to view all the information available on international applications under the PCT, the JPO has compiled it in a single webpage, which can be accessed via the following URLs. (http://www.jpo.go.jp/seido/kokusai/kokusai_shutugan1/index.html (Japanese) and <http://www.jpo.go.jp/english/applications/applications/index.html> (English)). This webpage includes information on the PCT (Treaty), Regulations under the PCT, and PCT International Search and Preliminary Examination, in addition to application procedures.

In addition, the JPO uploads information for users on international search and preliminary examination on its website. It also holds user workshops throughout Japan. The information can be viewed on the above web site (Japanese only).

(iv)

The JPO makes the following fundamental principles stipulated by Quality policy publicly available for the users as its goals in terms of quality:

- We grant robust, broad and valuable patents;
- We meet wide-ranging needs and expectations;
- We all dedicate ourselves to improving quality, cooperating with concerned persons and parties;
- We contribute to improving the quality of patent examination globally;
- We continually improve operations;
- We raise the knowledge and capabilities of our staff.

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.

削除: International Search Report

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Communications with WIPO, designated and elected Offices, shall be assumed by the International Policy Division, the Examination Standards Office, and QMO (See 21.13).

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.*

(a)

The documents that make up the Quality Manual are provided as "reference documents".

(b)

The Quality Manual and all reference documents can be obtained through the intranet. Part of them is provided in the form of paper media as pointed out in 21.10(v).

(c)

The latest versions are always updated and 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 and reference documents making up the Quality Manual include the items shown in (i)-(vi) above.

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.

(i)

The JPO has defined which documents are to be kept and where they are to be kept for the Quality Manual and reference documents that make up the Quality Manual.

(ii)

The Deputy Commissioner, with the Director-Generals of the first through fourth Patent Examination Departments and Appeals Department, who are the senior officers in charge of their respective

departments, reviews a management review regarding the availability of resources. And the results are documented and stored at the Administrative Affairs Division.

(iii)

Information on the training, expertise, and experience of each examiner is recorded and stored in a controlled manner.

(iv)(v)(vi)

Based on the results of both quality audits conducted on PCT applications by Quality Management Officers and consultations on PCT applications, the Deputy Commissioner, with the Director-Generals of the first through fourth Patent Examination Departments and Appeals Department, who are the senior officers in charge of their respective departments, reviews whether quality standards are being met (See 21.06, 21.12). The results are documented, reported to the Examination Departments, and stored at the Administrative Affairs Division.

(vii)

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

(viii)

The results of QMS review by the [Subcommittee on Examination](#) Quality Management consisting of external experts are recorded.

削除: Committee

(ix)

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

(x)(xi)

When problems are found, preventative plans of action are proposed in the sections concerned. The Deputy Commissioner, with the Director-Generals of the first through fourth Patent Examination Departments and Appeals Department, who are the senior officers in charge of their respective departments, reviews how to prevent recurrences. The results are documented, advised to members of Examination Departments, compiled into a written report, and stored in the Administrative Affairs Division. (See 21.06, 21.12).

(xii)

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

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 unity.*

(a)

When an examiner uses the [proprietary](#) 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 noted in the search report.

(b)

The information on viewed documents is automatically recorded in the system when using the [proprietary](#) search system developed by the JPO.

(c)

When corresponding to (vi) – (viii), that fact is all noted in the search report.

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.

As already indicated above.

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 year's report clear, for example using "track changes" or other form of highlighting. The template for the supplementary annual reports is therefore no longer used.

[End of document]