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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)

In this introduction, each Authority should include a summary of all changes to their quality management system that have taken place since the previous report on their Quality Management System, and any other matters considered to be interest in relation to quality management.

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. Authorities may include process charts if this would facilitate the understanding of an aspect of the report.

To further improve the quality of PCT International Search and Preliminary Examination, the JPO has continuously been enhancing its QMS, and further, conducts checks on all cases by directors or examiners delegated by the directors and consultations with other examiners.

Major changes that have taken place since the previous report are described below.

- In order to achieve efficient and high-quality examinations of AI-related inventions, the JPO inaugurated the Team for Supporting AI Examinations in 2021, which consists of experts on AI examinations, to accumulate and share knowledge on the latest AI-related technologies and case examples of examination results. In October 2023, the JPO increased the number of experts on AI examinations from 13 to 39 and assigned one expert, in principle, to each technical division to enhance and unify its consultation support for AI-related inventions, as it is expected that AI will be utilized in creative processes in a wider range of fields to a greater degree than previously possible.

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 specified by top management.
- (c) An organizational chart showing all those bodies and individuals responsible for the QMS.

(a)

In April 2014, the JPO released its “Quality Policy on Patent Examination” that was uploaded on the JPO’s website.

https://www.jpo.go.jp/e/introduction/hinshitu/shinsa/tokkyo/shinsa_policy.html

(b)

JPO Commissioner and Deputy Commissioner are responsible for the development and implementation of the quality management system. JPO Deputy Commissioner, based on the Commissioner’s instructions, generally organizes and manages important issues concerning technologies out of patent examination practices at the JPO.

(c)

The organizational chart of the JPO for the quality management system is shown in Figure 1.

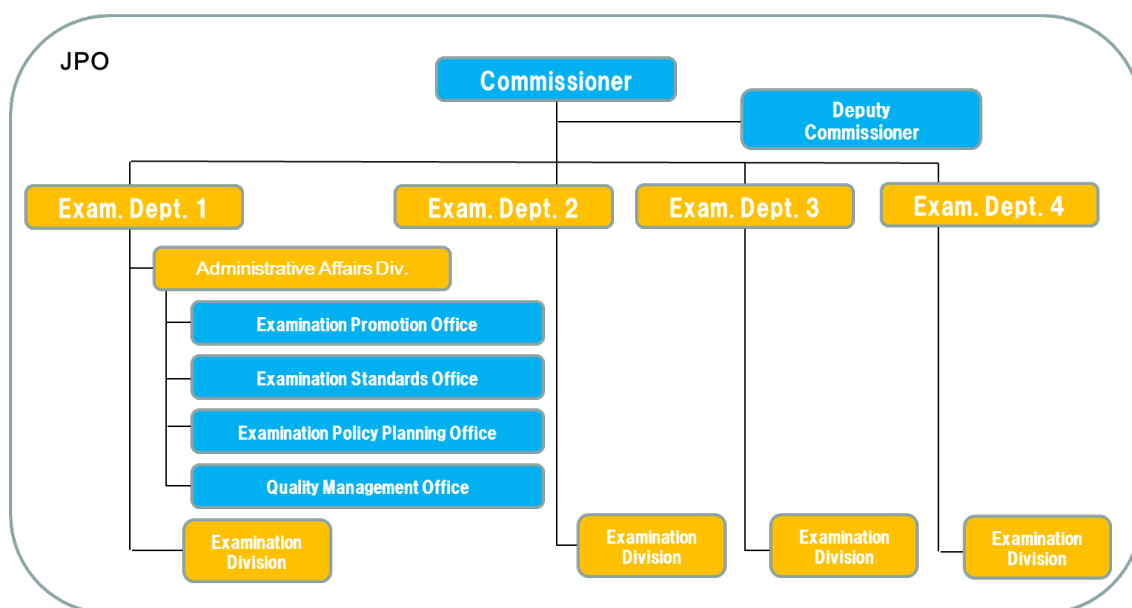


Figure 1 Organizational Chart of the JPO

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 to the relevant staff at the Authority	✓		
21.09		(a)	Performance of a yearly internal review of the QMS in/to	✓		
		(b)	determine the extent to which the QMS is aligned with 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			Risk and opportunities are addressed that can affect the QMS and the conformity of search and examination	✓		
21.13			Arrangements for establishing risk-based practices to	✓		
	(i)	(a)	understand issues that affect its ability to achieve intended results of the QMS	✓		
		(b)	understand the needs and expectations of interested parties	✓		
	(ii)		identify risks and opportunities related to the performance of the QMS as a basis for planning	✓		
	(iii)		plan and implement actions to address risks and opportunities	✓		
	(iv)		check the effectiveness of the actions taken	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
	(v)	continuously update risks and opportunities.	✓		
21.15		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 technical 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 of records	✓		
	(iii)	Ensuring appropriate equipment to carry out S&E	✓		
	(iv)	Ensuring documentation according to Rule 34	✓		
	(v)	(a) Instructions to help staff understand and act according to 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	✓		
21.16	(i)	Control mechanisms to ensure timely issue of S&E reports	✓		
	(ii)	Control mech. regarding fluctuations in demand and backlog	✓		
21.17	(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, eliminate the causes and prevent issues from recurring	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
21.19	(a)	Contact person helping identify best practice between Authorities	✓		
	(b)	Contact person fostering continual improvement	✓		
	(c)	Contact person providing for effective communication with other Authorities for feedback and evaluation	✓		
21.20	(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	✓		
		Indication where and how the Authority makes its quality objectives publicly available	✓		
21.21		Established communication with WIPO and designated and elected Offices	✓		
21.22		QMS of Authority clearly described and documented	✓		
21.23	(a)	Material making up the reference of quality procedures and processes for staff and management has been prepared and distributed	✓		
	(b)	Media available to support the reference material	✓		
	(c)	Document control measures are taken	✓		
21.24		Items which should be documented in the reference of quality procedures and processes	✓		
	(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.	✓		
21.25	(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	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
	(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	✓		
21.26	(i)	Recording of the databases consulted during search	✓		
	(ii)	Recording of keywords, combination of words and truncations during search	✓		
	(iii)	Recording of the languages used during search	✓		
	(iv)	Recording of classes and combinations thereof consulted during search	✓		
	(v)	Recording of a listing of all search statements used in databases consulted	✓		
	(vi)	Records about other information relevant to the search	✓		
	(vii)	Records about limitation of search and its justification	✓		
	(viii)	Records about lack of clarity of the claims	✓		
	(ix)	Records about lack of unity	✓		
21.27		Report on its own internal review processes	✓		
21.28-21.30		Additional information on further inputs to its internal reviews	✓		
21.31		Initial report called for by paragraph 21.31	✓		

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 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 these activities with the Director-Generals of the first through fourth Patent Examination Departments and the Trial 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 communicating and 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 examination department, manages quality through analyzing and evaluating the quality of patent examination. The Committee analyzes 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 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.

A Committee consisting of external experts checks whether the QMS 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 practical experiences 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 QMS.

The Deputy Commissioner reviews the QMS for patent examination based on the results received from the Quality Management Internal Committee as well as on other information received (See 21.09) with the Director-Generals of the first through fourth Patent Examination Departments and the Trial 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 standardize examiners' practices.

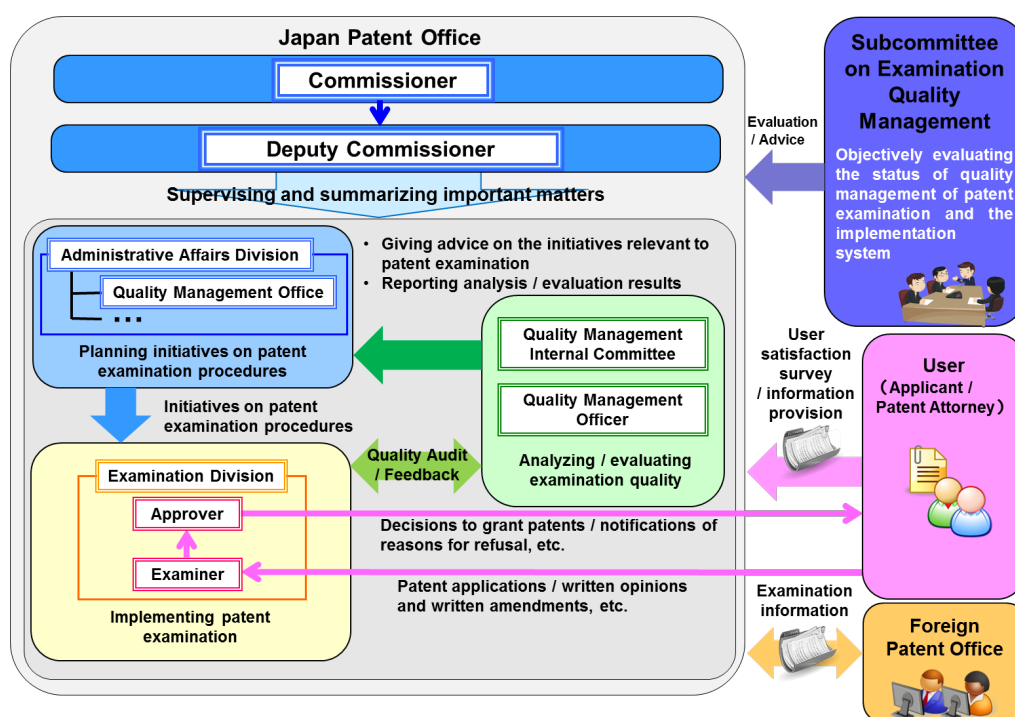


Figure 2 Outline of the QMS

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 by the relevant staff at the respective Authority.

(a)

The Deputy Commissioner, with the Director-Generals of the first through fourth Patent Examination Departments and the Trial 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, twice a year.

(b)(c)

At the beginning of each fiscal year, the Deputy Commissioner shares information with the Director-Generals of the first through fourth Patent Examination Departments and the Trial and Appeal Department, who are the senior officials in charge of their respective departments, and conducts comprehensive reviews on the JPO's planned initiatives on examinations, including the quality objectives, from the perspectives of: (1) handling examinations efficiently; (2) improving the environment for retrieval of documents; (3) applying legal requirements and examination guidelines; (4) ensuring quality management; and (5) fostering human resources. After that, the results of the reviews, including the reviews on the quality objectives, are to be notified to examiners.

21.09 Indicate whether top management or delegated officers of the Authority perform an internal review of the QMS in accordance with paragraphs 21.27-21.30:

(a) at least once per year (cf. paragraph 21.27);

(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 21.27, 21.29(i));

to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.27, 21.29(i));

(c) in an objective and transparent way (cf. paragraph 21.27);

(d) using input including information according to paragraphs 21.29 (ii)-(vi);

(e) recording the results (cf. paragraph 21.30).

(a)

The Deputy Commissioner shares information with the Director-Generals of the first through fourth Patent Examination Departments and the Trial and Appeal Department, who are the senior officials in charge of their respective departments, and conducts management reviews on the QMS about twice a week, if necessary. In addition, the Deputy Commissioner conducts a comprehensive management review on the QMS at the beginning of each fiscal year and the latter half of each fiscal year.

(b)(d)

The input to the management review includes:

- Results of review on the quality audits (See 21.17 (i));
- Results of consultations among examiners on PCT applications (See 21.17 (i));
- Statistical data related to quality (See 21.17 (ii));
- Results of analysis on discrepancies between ISRs and FAs in the national phase (See 21.17 (ii));
- Feedbacks from users (See 21.20);
- Corrective actions and preventive actions taken for detected 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; and
- Evaluations and advice from the External Expert Committee.

(c)(e)

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

21.10 Indicate whether top management of the Authority promote practices to ensure that risks and opportunities that can affect its QMS and the conformity of international search and examination are addressed.

The Deputy Commissioner understands current issues from a lot of perspectives through management reviews, and works to solve the problems. (See 21.06, 21.08 and 21.09)
This process includes ensuring that risks and opportunities that can affect the QMS and the conformity of international search and examination are addressed.

2. RISK-BASED PRACTICES

21.11 Explanatory note: Each Authority should establish its own risk-based practices to enable the Authority to determine factors that could cause operational processes and its quality management system to deviate from requirements or planned results, to put in place preventive controls to minimize negative effects, and to make use of opportunities as they arise.

21.12 Explanatory note: It is open to each Authority to set up its own arrangements to determine the effect of uncertainty on objectives. Paragraph 21.13 provides a guide to the basic components of risk-based practices as an element of QMS. There is no requirement for formal methods of risk management or a documented risk management process.

(Note: These points are informative. No response is required by the template to paragraphs 21.11 and 21.12).

21.13 Arrangements for establishing risk-based practices

Provide information on the arrangements that your Authority has made to:

- (i) (a) understand issues that affect its ability to achieve intended results of the QMS, and*
 - (b) understand the needs and expectations of interested parties;*
- (ii) identify risks and opportunities related to the performance of the QMS as a basis for planning;*
- (iii) plan and implement actions to address risks and opportunities;*
- (iv) check the effectiveness of the actions taken; and*
- (v) continuously update risks and opportunities.*

21.14 Explanatory note: All processes of the QMS present differing levels of risk in terms of the Authority's ability to meet its objectives, and the effects of uncertainty are not the same for all Authorities. Each Authority is responsible for the actions it decides to take to address risks and opportunities.

(Note: This point is informative. No response is required by the template to paragraph 21.14).

In order to establish risk-based practices, the JPO has been working on the items described in 21.13, as the following:

(i)(a), (ii)

Through the process described in 21.10, the JPO understands issues that affect its ability to achieve intended results of the QMS, and identifies risks and opportunities related to the performance of the QMS.

(i)(b)

As shown in 21.20, the JPO understands the needs and expectations of interested parties, by receiving information from users at any time, conducting user satisfaction surveys and holding meetings with users.

(iii)(iv)(v)

The "Quality Manual" states that quality management should be conducted in accordance with the PDCA cycle (Plan, Do, Check, Act) in order to maintain and improve examination quality, and the JPO thereby realizes the processes 21.13 (iii)-(v).

Especially, as shown in 21.15, the JPO has prepared enough resources to ensure that the QMS properly functions as planned, and reallocates them according to changes in circumstances.

3. RESOURCES

21.15 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)

As of 2023, there are a total of 1,663 examiners working at the JPO, which include 496 (assistant) fixed-term examiners. In the four Examination Departments and 38 Examination Offices, around 130 managers are assigned to manage examination works, including quality management.

At the JPO, patent examiners carry out searches and examinations. These patent examiners generally have a technological educational background at universities or colleges and have at the minimum of a bachelor's degree. Some examiners have 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 its employees.

As a provisional measure to cope with further increasing backlogs, from fiscal year 2004 to 2009, the JPO hired highly specialized, external experts as fixed-term examiners. The JPO employed fixed-term examiners also from fiscal years 2014 to 2017. When hiring them, the JPO gave the candidates an examination that is equivalent to the Examination for Comprehensive Service. In addition, it conducted character tests for them and strictly evaluated their natures and personalities.

Even after hired as examiners, examiners have opportunities to take various training courses to enhance their knowledge and skills, such as: (1) knowledge about international searches and preliminary examinations; (2) knowledge about specific technologies; (3) language skills to deal with the internationalization of the intellectual property system; (4) knowledge and know-how about prior art searches; (5) knowledge to utilize intellectual property.

Moreover, assistant examiners have the opportunity to receive specified English language training before they are promoted to examiners. Also, in addition to English, examiners can attend training courses to learn other foreign languages such as French, German, and Chinese.

(ii)

Part of the staff at office work and management divisions is examiners transferred from the Patent Examination Divisions, and they have sufficient knowledge about the PCT system. Other staff is also properly trained in the entire PCT system, its search/examination process, and the details 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 conducting searches on 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 works, and are periodically updated and upgraded upon their requests 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 documents and non-patent literature. Retrieval styles that have been used in conducting searches, and document sets obtained based on the retrieval styles, can automatically be recorded. This enables examiners to share their knowledge about searches with each other, which is useful in terms of quality audits. Furthermore, the JPO has access to external databases in order to conduct prior art searches.

The JPO has set up support functions that help examiners issue ISRs or IPERs, by using a drafting system. The support functions under the system include simultaneous drafting of necessary documents, automatically import of bibliographic data to drafting documents, and checking of the contents of reports. Moreover, this enables the JPO to administer and approve procedures electronically for PCT applications.

Also, at the JPO, a dual-display terminal is being used by each examiner to facilitate screening of patent documents and non-patent literature with a larger-size display.

- Search Indexes for Searching Patent Documents

For efficient searches on Japanese patent documents, the JPO has set its original classification, called "File Index (FI)," and search index, called "F-term (File forming term)." FI is a classification system subdividing the IPC for Japan-specific technologies. F-terms are search indexes which are composed of various technical aspects in approximately 1,600 out of 2,500 technical areas (themes) to which FI belongs. JPO's examiners can combine full-text search with FI/F-terms. Because FI/F-terms and full-text search can be used together, JPO examiners can narrow down patent document groups and conduct more efficient and highly accurate searches. FI/F-terms are allocated to foreign patent documents by utilizing AI technology. When searching foreign patent documents, examiners can also use FI/F-terms in addition to IPC, CPC and full-text search.

- Tools and Equipment for Non-patent Literature Search

When conducting prior art searches in specific technical fields, such as computer software, highly competitive cutting-edge technologies, and technical standards, IP offices need to thoroughly search both patent documents and non-patent literatures.

Therefore, the JPO stores highly useful non-patent literature in its internal database. In the uniquely developed search system, the JPO establishes a framework in which searches can be conducted seamlessly for both patent documents and non-patent literature.

In recent years, the JPO improved its infrastructure for searching documents on technical standards and documents on standards, which were submitted in the process of establishing the standards. The JPO expanded the scope of documents on standards that can be stored in its internal database by collaborating with standards setting organizations (SSOs).

- Search Indexes for Non-patent Literature

The JPO sets up search index referred to as "CS-term" for efficient searches on 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.

Like F-terms that are used for searching patent documents, JPO's examiners can combine full-text search with CS-terms. They can narrow down non patent literature groups with using CS-terms and full-text search, leading to more effective and accurate searches.

(iv)

The JPO possesses a substantial amount of very useful documentation with a focus on patent documents. The JPO secures access of the examiners there to the properly arranged and maintained minimum documentation under Rule 34, including patent gazettes and non-patent literature. The examiners have access to the JPO's uniquely developed search systems,

collections of the internal library and external databases. Thanks to these, the JPO meets the requirements for searches on minimum documentation as an ISA.

(v)

- The JPO formulated its “Quality Policy” that outlines fundamental policies of quality management for patent examinations, including international searches and international preliminary examinations; its “Quality Manual” that outlines initiatives for improving the quality of patent examinations as well as the roles of the organization and the staff; and other documents for quality management. JPO staff can obtain the latest versions of these documents from the JPO’s website or internal database. The main documents are as follows;

- “Quality Policy”

This outlines fundamental policies of quality management for patent examinations, which is published on the JPO’s website.

<https://www.jpo.go.jp/e/introduction/hinshitu/shinsa/policies.html>

- “Quality Manual”

This is designed to document the quality management system consisting of both the quality management activities for patent examinations based on the fundamental policies stipulated in the Quality Policy; and the systems for implementing these activities. The Manual is also published on the JPO’s website. In recent years, with a view to responding to changes in the social environment in the age of With-Corona and Digital Transformation, the means of communication with applicants and examiners have been enhanced, online systems have been introduced in the quality management activities, and the form of implementation of consultations have been expanded. Based on these initiatives, we revised the “Quality manual”, documenting the QMS, and published in 2022.

https://www.jpo.go.jp/e/introduction/hinshitu/shinsa/tokkyo/tokkyo_manual.html

- Other documents that were formulated for quality management

- “PCT International Search and Preliminary Examination Guidelines”

The Guidelines are available on the WIPO website. A Japanese translation of the Guidelines is available on the JPO’s website.

- “Handbook for PCT International Search and Preliminary Examination in the Japan Patent Office”

In October 2015, 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 the “PCT Handbook”. It is available in both Japanese and English. Since being published in October 2015, it has been updated based on the revisions made to regulations or the Guidelines.

https://www.jpo.go.jp/e/system/patent/pct/chosa-shinsa/pct_handbook.html

The PCT Handbook is available to examiners in electronic form. 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.

- The scheme of the IPC

The scheme of the IPC lists classification entries of IPC (International Patent Classification). This classification table has a structure in which entire technical fields are subdivided into levels of section, class, subclass, main group, and subgroup.

- The scheme of FI, FI handbook, F-term lists

The scheme of FI lists classification entries of FI (File Index); FI handbook provides supplementary explanations about FI and explains FI-related fields, etc.; and F-term lists are lists of F-terms by theme, which are JPO's unique search indexes.
<https://www.j-platpat.inpit.go.jp/p1101>

- Computer System Operations Manuals

The JPO has manuals that explain the details about its uniquely developed search systems. These manuals can be viewed on the intranet. In addition, the JPO provides examiners with training on how to operate the systems, by using handouts that we made based on the manuals.

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

Persons recruited by the JPO are required to attend two training courses and to pass examinations set for each of the courses before they are promoted to examiners. Total hours of the two courses are around 250 hours. Lecturers for the training programs are university professors, patent attorneys, and examiners. The training programs include training on international treaties and their rules, including the Patent Cooperation Treaty (PCT), the contents of the PCT International Search and Preliminary Guidelines, and operating practices of international searches and preliminary examinations.

- OJT by supervising examiners

At the JPO, new recruits receive trainings to conduct examinations as assistant examiners for 2~4 years, depending on their prior experiences, while working under the guidance of supervising examiners.

- Training to acquire knowledge on technologies

In order to gain knowledge about cutting edge, high level technologies, examiners are given various opportunities, such as attending technological training programs, visiting businesses, internships, and studying at domestic universities and overseas universities. Also, in order to continually foster examiners who can deal with examinations on AI and IoT technologies, the JPO has set its internal training courses consisting of several training

programs on AI and IoT technologies, and provided opportunities for its examiners to take these trainings.

- Training to acquire knowledge and know-how in conducting searches on prior art documents
In order to acquire methods for searching foreign patent documents or non-patent literature and appropriate and efficient search methods utilizing search support tools, examiners are given opportunities to attend specific training programs, when necessary.
- Language training
For persons recruited by the JPO, opportunities to receive language training in English and other foreign languages, such as French, German, and Chinese are also given, when necessary.
- Training on Quality Management
Persons recruited by the JPO are required to take training courses, in order to gain knowledge about the contents and concepts of the Quality Policy and the Quality Manual. In addition, all the staff members at the JPO take an annual quality test in an e-learning format, which helps them develop and improve their basic knowledge of the fundamental principles stipulated in the Quality Policy, laws and regulations, the Examination Guidelines, the Handbook for PCT International Search and Preliminary Examination, prior art searches, etc. necessary for examination practice. Also, the JPO has continued to enhance and improve the contents of the training programs for quality management.

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.

4. MANAGEMENT OF ADMINISTRATIVE WORKLOAD

21.16 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 case 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.

5. QUALITY ASSURANCE

21.17 In accordance with the Guidelines, the following are required quality assurance measures for timely issue of search and examination reports of a high quality. Indicate how the following are implemented, including the use of any checklists to verify reports before their issue or for monitoring the quality 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 searches and international preliminary examinations has been maintained and enhanced by checks carried out on all cases by directors or persons delegated by the directors, and through consultations conducted with other examiners.

In addition, by utilizing a uniquely developed check system, examiners confirm whether there are any defects in terms of formalities in bibliographic items in the ISRs and IPERs that have been prepared by themselves, before checks carried out on the ISRs and IPERs by directors or persons delegated by them.

Furthermore, "quality audits" have become standard practice from fiscal year 2014 after they were conducted on a trial basis for two years. The quality audits include additional searches as needed. Quality Management Officers take random samples of cases before any notices are sent to applicants and review them to check whether they comply with the International Search and International Preliminary Examination Guidelines. Feedback on the results of quality audits are, in principle, given to examiners in charge, after the Quality Management Officers and Directors have discussed them. The results of the analyses on quality audits, with the analysis results of user reviews and related statistical information, are presented to the Deputy Commissioner (and Director-Generals of the first through fourth Patent Examination Departments and the Trial and Appeal Department, who are senior officers in charge of their

respective departments). After that, the sections concerned take them into consideration to improve the specific process for higher examination quality. Also, these results are provided to directors in each of the Examination Departments, in order to support and improve their quality management activities. (See 21.06).

Moreover, the JPO continues to conduct a pilot program to analyze the following case, in which discrepancies on search and examination results between the JPO and other IP 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.

The followings are major initiatives that the JPO has been undertaking in recent years to enhance the quality of examinations:

- Aiming to produce high-quality products in international PCT applications, the JPO implemented the PCT Collaborative Search and Examination Pilot Project from July 2018 to June 2020. In this project, a main ISA, in collaboration with peer ISAs, decides on patentability for a selected PCT application and provides a single international search report to the applicant. The IP5 evaluated the pilot program from July 2020 to June 2023 and adopted the final report of the pilot program in June 2023;
- In order to achieve efficient and high-quality examinations of AI-related inventions, the JPO inaugurated the Team for Supporting AI Examinations in 2021, which consists of experts on AI examinations, to accumulate and share knowledge on the latest AI-related technologies and case examples of examination results. JPO examiners can now consult the experts in examinations of AI-related inventions. In October 2023, the JPO increased the number of experts on AI examinations from 13 to 39 and assigned one expert, in principle, to each technical division to enhance and unify its consultation support for AI-related inventions, as it is expected that AI will be utilized in creative processes in a wider range of fields to a greater degree than previously possible;
- The JPO also proposed a project to collect materials on the examination practices of the IP5 Offices on AI-related inventions, as the first project based on a roadmap for cooperation in the field of NET and AI, at the IP5 Heads of Office Meeting held in 2022 and proceeded with a comparative table compiling relevant legal texts, examination guidelines, examination case studies, etc. The comparative table was endorsed at the IP5 Heads of Office Meeting held in June 2023 and published on the IP5 website; and
- The JPO is constantly reviewing its QMS with the aim of realizing high quality examination that are internationally trusted, and with a view to responding to changes in the social environment in the age of With-Corona and Digital Transformation. This includes an introduction and utilization of online systems for interview examinations and the quality management activities, as well as continuous improvements in the operation of the systems, to enhance means of communication between applicants and examiners constantly. We have also been reviewing the form of implementation of consultations to share effective search methods in search systems which are becoming more sophisticated by the day and to share examination know-how among examiners.

(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 the Trial 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. (See 21.06, 21.09).

6. COMMUNICATION

Inter-Authority communication:

21.18 *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 21.18)

21.19 *Provide the name, job title and contact details of the Authorities designated quality contact person who will take responsibility for:*

- (a) helping identify and disseminate best practice among Authorities;*
- (b) fostering continual improvement; and*
- (c) providing for effective communication with other Authorities to allow for prompt feedback from them so that potential systemic issues can be evaluated and addressed.*

As of April 1, 2024:

- International Policy Division, Multilateral Policy Office
 - TAUCHI Koji (Mr.) (Director)
 - HOSHINO Sachiko (Ms.) (Deputy Director)
 - YOKOYAMA Kyoko (Ms.) (Assistant Director)
 - IHA Yuki (Ms.) (Administrative Officer)
- Administrative Affairs Division, Examination Standards Office (Especially on (a))
 - HOSHINO Masayuki (Mr.) (Director)
 - KIKITSU Noritane (Mr.) (Deputy Director)
 - SHOJI Anzu (Ms.) (Assistant Director)
- Administrative Affairs Division, Quality Management Office (Especially on (b) & (c))
 - MATSUURA Akiko (Ms.) (Director)
 - FUJISAKI Akio (Mr.) (Deputy Director)

Communication and guidance to users:

21.20 *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.

Indicate 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 ISR and the IPER prepared by the examiner. This ensures appropriate communications between applicants and examiners in individual cases.

Also, information from users is received at the Quality Management Office (QMO) by telephone,

e-mail or the form on the JPO's website. In addition, users can provide information in user satisfaction surveys conducted by the JPO, which are described in (ii) below, and at informal meetings to have discussions with the JPO. Information provided by users is utilized for improving the quality of examinations.

Moreover, when it is found that JPO's response to any individual case is inappropriate, feedback is made to the examiner in charge as required, if the JPO gets permission from the user to do so. On top of this, corrective or preventive actions are taken by notifying all examiners, ensuring that the specific case would not be identified.

(ii)

The QMO has been conducting user satisfaction surveys to monitor the level of user satisfaction and gain user opinions about the quality of the JPO's examination. In fiscal year 2023, the JPO conducted a survey on the quality of work products such as ISRs, targeting 592 applicants. Furthermore, the JPO conducts detailed analysis on the statistical data gathered from the surveys and on individual applications. The past survey results are available on the JPO's website (<https://www.jpo.go.jp/e/resources/report/user/>).

In addition, the JPO conducts opinion exchange meetings with companies to better understand user needs.

(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.

(<https://www.jpo.go.jp/system/patent/pct/index.html> (Japanese) or
<https://www.jpo.go.jp/e/system/patent/pct/index.html> (English))

This webpage includes information on the PCT (Treaty), Regulations under the PCT, and PCT International Search and Preliminary Examination Guidelines, in addition to application procedures.

In addition, the JPO uploads specific information and videos for users on international searches and preliminary examinations on its website

(https://www.jpo.go.jp/news/shinchaku/event/seminer/chizai_setumeikai.html) (Japanese only).

(iv)

As one of the objectives of its quality management, the JPO makes the following fundamental principles stipulated in its Quality policy publicly available for users:

- 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; and
- We raise the knowledge and capabilities of our staff.

Also, the JPO has set up its goals to be achieved, publicizing them every fiscal year. The goals for fiscal year 2023 include working to ensure that the percentage of users responding 4 or higher on a scale of 5 is 65% or higher in terms of their satisfaction with communication with examiners, and that examiners conduct interview examinations whenever applicants request them, in principle.

https://www.meti.go.jp/policy/policy_management/jissityou-hyouka/2023/R5mokuhyou.html
(Japanese)

21.21 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.

In general, the JPO sends members of its International Policy Division, Multilateral Policy Office, and other concerned departments and divisions to meetings held by WIPO. Furthermore, the JPO has discussions with designated offices or elected offices at bilateral meetings and multilateral meetings.

Every time the JPO receives any feedback from WIPO, the designated offices, or elected offices, the concerned departments and divisions at the JPO discuss possible initiatives to deal with issues pointed out in their feedback. (See 21.18)

7. DOCUMENTATION

21.22 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 by documenting the procedures and processes affecting the quality of work as a reference for staff and management at the Authority (see paragraph 21.23).*

(Note: This point is informative. No response is required by the template to paragraph 21.22)

21.23 *The material that makes up the reference for staff and management at the Authority serves to document the procedures and processes affecting the quality of work, such as classification, search, examination and related administrative work. In particular, the reference indicates where to find instructions on the procedures to be followed.*

For the purposes of this report indicate:

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

(a)

The JPO's "Quality Manual" contains reference documents, which describe the process or works that can affect the quality of the operating procedures under the PCT, such as assigning classifications and conducting examinations.

(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 21.15(v).

(c)

The JPO's "Quality Manual" contains the records of revisions. Also, whenever any revisions are made, the latest version is updated and available on the intranet.

21.24 Indicate whether the material making up the reference of quality procedures and processes 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.

21.25 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's Quality Manual and reference documents that make up the Quality Manual are uploaded on its website and intranet. Also, links to these reference documents are included in the Quality Manual to make them accessible.

(ii)

The Deputy Commissioner, together with the Director-Generals of the first through fourth Patent Examination Departments and the Trial and Appeal Department, who are senior officers in charge of their respective departments, conducts a management review on the availability of resources. And the results are documented and stored at the Administrative Affairs Division.

(iii)

At the JPO, information on trainings, expertise, and experiences of each examiner is recorded and stored in its internal database.

(iv)

Based on the results of both quality audits conducted on PCT applications by Quality Management Officers and consultations on PCT applications, the Deputy Commissioner, together with the Director-Generals of the first through fourth Patent Examination Departments and the Trial and Appeal Department, who are senior officers in charge of their respective departments, reviews whether the quality standards are being met (See 21.06, 21.17). The results are documented, reported to the Examination Departments, and stored at the Administrative Affairs Division.

(v)

The results of quality audits and consultations as well as the results of reviews for (iv) are recorded and stored in the JPO's internal database.

(vi)

The JPO digitally records the operating procedures of international searches and preliminary examinations in its case management system. Also, a part of the search process is recorded in the search system, which was developed independently by the JPO.

(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 External Expert Committee are recorded.

(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 the Trial 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, 21.17).

(xii)

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

8. SEARCH PROCESS DOCUMENTATION

21.26 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 a case where searches were conducted with other database than that for the JPO, at least the information (i) (and that of (ii) in certain instances) is noted in search reports.

(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.

9. INTERNAL REVIEW

21.27 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.

21.28-21.30 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.

10. ARRANGEMENTS FOR AUTHORITIES TO REPORT TO THE MIA

21.31 There are two stages in the reporting arrangements outlined in Chapter 21: the initial report called for by paragraph 21.31(a), and supplementary annual reports in accordance with paragraph 21.31(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.

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